EXHIBIT A

CT Corporation

Service of Process Transmittal

05/28/2019
CT Log Number 535563359

TO: Serviceof Process
CVS Health Companies
1 Cvs Dr Mail Code 1160
Woonsocket, RI 02895-6146

RE: **Process Served in Mississippi**

FOR: CVS Pharmacy, Inc. (Domestic State: RI)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Roclavall County, Pltf. vs. Purdue Pharma, L.P., et al., Dfts. // To: CVS Health *Name discrepancy noted.*
DOCUMENT(S) SERVED:	LETTER, CITATION, RETURN, PETITION
COURT/AGENCY:	439 District Court Rockwall County, TX Case # 1190503
NATURE OF ACTION:	Product Liability Litigation - Drug Litigation - Opioids
ON WHOM PROCESS WAS SERVED:	C T Corporation System, Flowood, MS
DATE AND HOUR OF SERVICE:	By Certified Mail on 05/28/2019 postmarked on 05/22/2019
JURISDICTION SERVED :	Mississippi
APPEARANCE OR ANSWER DUE:	At or before 10:00 A.M. of the Monday next after the expiration of 20 days after the date of service hereof (Document(s) may contain additional answer dates
ATTORNEY(S) / SENDER(S):	Matthew R. McCarley FEARS NACHAWATI, PLLC 5473 Blair Road Dallas, TX 75231 214-890-0711
REMARKS:	Please note even though the documents are directed to CVS HEALTH, our records indicate that we are agent for all entities beginning with this name and they all share the same delivery instructions.
ACTION ITEMS:	CT has retained the current log, Retain Date: 05/29/2019, Expected Purge Date: 06/03/2019 Image SOP Email Notification, Serviceof Process Service_of_Process@cvs.com
SIGNED:	C T Corporation System
ADDRESS:	645 Lakeland East Drive Suite 101 Flowood, MS 39232
TELEPHONE:	214-932-3601

Secretary of State
Service of Process
P.O. Box 12079
Austin, Texas 78711-2079

RETURN
SERVICE
REQUESTED

neopost
05/22/2019
US POSTAGE $014.55[0]

ZIP 78701
041L12204064

CERTIFIED MAIL™

Secretary of State
Service of Process
P.O. Box 12079
Austin, Texas 78711-2079

7190 1046 4701 0104 8841

Return Receipt (Electronic)

2019304903-11

CVS Health
c/o CT Corporation System
645 Lakeland East Drive, Suite 101
Flowood, MS 39232

The State of Texas

Service of Process
P.O. Box 12079
Austin, Texas 78711-2079

David Whitley
Secretary of State

Phone: 512-463-5560
Fax: 512-463-0873
Dial 7-1-1 For Relay Services
www.sos.state.tx.us

2019-304903-11

Include reference number in all correspondence

May 22, 2019

CVS Health
c/o CT Corporation System
645 Lakeland East Drive, Suite 101
Flowood, MS 39232

RE: Rockwall County VS Purdue Pharma, L.P., et al
439th District Court Of Rockwall County Texas
Cause No. 1190503

Dear Sir/Madam,

Pursuant to the Laws of Texas, we forward herewith by CERTIFIED MAIL, return receipt requested, a copy of the process received by the Secretary of State of the State of Texas on May 20, 2019.

CERTIFIED MAIL #71901046470101048841

Refer correspondence to:

Matthew R. McCarley
Fears Nachawati, PLLC
5473 Blair Rd
Dallas, TX 75231

Sincerely,

Service of Process
Government Filings
512-463-1662
GF/mr
Enclosure

CIVIL CITATION

THE STATE OF TEXAS

439th District Court

Cause No. 1-19-0503

THE STATE OF TEXAS
NOTICE TO DEFENDANT: "You have been sued.". You may employ an attorney. If you or your attorney do not file a written answer with the clerk who issued this citation by 10:00 A.M. on the Monday next following the expiration of twenty days after you were served this citation and petition, a default judgment may be taken against you.

TO:
CVS Health
By serving the Secretary of the State of Texas
P.O. BOX 12079
AUSTIN, TEXAS 78711-2079

You are hereby commanded to appear before the 439th District Court of Rockwall, Texas in Rockwall, Texas, at the Rockwall County Courthouse, 1111E Yellowjacket Lane, Suite 200, in Rockwall, Texas by filing a written answer to Plaintiff's ORIGINAL PETITION at or before 10:00 A.M. of the Monday next after the expiration of 20 days after the date of service hereof, a copy of which accompanies this citation, in cause number 1-19-0503, styled Rockwall County Vs Purdue Pharma LP.,Purdue Pharma, Inc.,The Purdue Frederick Company,Cephalon, Inc.,Teva Pharmaceutical Industries, Ltd.,Teva Pharmaceuticals USA, Inc.,Janssen Pharmaceuticals, Inc.,Johnson & Johnson,Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.,Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.,Endo Health Solutions, Inc.,Endo Pharmaceuticals, Inc.,Abbott Laboratories,Knoll Pharmaceutical Company,Allergan PLC f/k/a Actavis PLC,Allergan Finance LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.,Allergan Sales LLC,Allergan USA Inc.,Insys Therapeutics, Inc.,Insys Manufacturing LLC,McKesson Corporation,McKesson Medical-Surgical, Inc.,Cardinal Health 110 LLC,Cardinal Health 200, LLC,Cardinal Health 414 LLC,AmerisourceBergen Drug Corporation,Mallinkrodt PLC,Mallinkrodt LLC,Mallinkrodt Brand Pharmaceuticals,SpecGX, LLC,Abbvie, Inc.,Knoll Pharmaceutical Company,CVS Health,Walgreens Boots Alliance, Inc. a/k/a Walgreen Co.,Wal-Mart Stores, Inc.,Richard Andrews, MD,Theodore Okechuku, MD,Nicolas Padron, MD.

Said Petition was filed in the 439th District Court on APRIL 10, 2019 by MATTHEW R. MCCARLEY, Attorney for Plaintiff, whose address is 2801 NETWORK BLVD SUITE 820 FRISCO TX 75034

ISSUED AND GIVEN UNDER MY HAND AND SEAL of Court at office this on this the 12th day of April, 2019

Lea Carlson, District Clerk
Rockwall County, Texas
By: _____, Deputy
Jeni Holt

DISTRICT COURT OF ROCKWALL COUNTY TEXAS

Defendant copy

304903-(1

RETURN OF SERVICE

Cause No. : 1-19-0503 **439th District Court**
Rockwall County Vs Purdue Pharma L.P.,Purdue Pharma, Inc.,The Purdue Frederick Company,Cephalon, Inc.,Teva Pharmaceutical Industries, Ltd.,Teva Pharmaceuticals USA, Inc.,Janssen Pharmaceuticals, Inc.,Johnson & Johnson,Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.,Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.,Endo Health Solutions, Inc.,Endo Pharmaceuticals, Inc.,Abbott Laboratories,Knoll Pharmaceutical Company,Allergan PLC f/k/a Actavis PLC,Allergan Finance LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.,Allergan Sales LLC,Allergan USA Inc.,Insys Therapeutics, Inc.,Insys Manufacturing LLC,McKesson Corporation,McKesson Medical-Surgical, Inc.,Cardinal Health 110 LLC,Cardinal Health 200 LLC,Cardinal Health 414 LLC,AmerisourceBergen Drug Corporation,Mallinkrodt PLC,Mallinkrodt LLC,Mallinkrodt Brand Pharmaceuticals,SpecGX, LLC,Abbvie, Inc.,Knoll Pharmaceutical Company,CVS Health,Walgreens Boots Alliance, Inc. a/k/a Walgreen Co.,Wal-Mart Stores, Inc.,Richard Andrews, MD,Theodore Okechuku, MD,Nicolas Padron, MD

Executed when copy is delivered:
This is a true copy of the original citation, was delivered to defendant_____, on the _____ day of _____, 20____.

_____, Officer
_____, County, Texas
By: _____, Deputy

ADDRESS FOR SERVICE:
CVS Health
By serving the Secretary of the State of Texas
P.O. BOX 12079
AUSTIN, TEXAS 78711-2079

OFFICER'S RETURN

Came to hand on the _____ day of _____, 20____, at _____, o'clock ___.m., and executed in _____ County, Texas by delivering to each of the within named defendants in person, a true copy of this Citation with the date of delivery endorsed thereon, together with the accompanying copy of the ORIGINAL PETITION at the following times and places, to-wit:

Name	Date/Time	Place, Course and Distance from Courthouse

And not executed as to the defendant(s),_____
The diligence used in finding said defendant(s) being:_____
And the cause or failure to execute this process is:_____
And the information received as to the whereabouts of said defendant(s) being:_____

FEES:
Serving Petition and Copy $_____
Total: $_____

_____, Officer
_____ County, Texas
By: _____, Deputy

_____
Affiant

COMPLETE IF YOU ARE A PERSON OTHER THAN A SHERIFF, CONSTABLE, OR CLERK OF THE COURT.
In accordance with Rule 107: The officer or authorized person who serves, or attempts to serve, a citation shall sign the return. The signature is not required to be verified. If the return is signed by a person other than a sheriff, constable or the clerk of the court, the return shall be signed under penalty or perjury and contain the following statement.
" My name is _____, my date of birth is _____, and my address is
(First, Middle, Last)
_____,
(Street, City, Zip)
I DECLARE UNDER PENALTY OF PERJURY THAT THE FORGOING IS TRUE AND CORRECT.
Executed in _____ County, State of _____, on the _____ day of _____.

_____
Declarant/Authorized Process Server

_____
(Id # & expiration of certification)

Cause No. 1-19-0503

Rockwall County	§	**In the District Court**
	§	
Plaintiff,	§	
v.	§	
	§	
Purdue Pharma, L.P.; Purdue Pharma Inc.; The Purdue Frederick Company; Cephalon, Inc.; Teva Pharmaceutical Industries, Ltd; Teva Pharmaceuticals USA, Inc.; Janssen Pharmaceuticals, Inc.; Johnson & Johnson; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Abbott Laboratories; Knoll Pharmaceutical Company; Allergan PLC f/k/a Actavis PLC; Allergan Finance LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Allergan Sales LLC; Allergan USA Inc.; Insys Therapeutics, Inc.; Insys Manufacturing LLC; McKesson Corporation; McKesson Medical-Surgical Inc.; Cardinal Health, Inc.; Cardinal Health 110 LLC; Cardinal Health 200 LLC; Cardinal Health 414 LLC; Amerisource Bergen Drug Corporation; Mallinckrodt PLC; Mallinkrodt, LLC; SpecGx, LLC; Abbvie, Inc.; Knoll Pharmaceutical Company; CVS Health; Walgreens Boots Alliance, Inc., a/k/a Walgreen Co.; Wal-Mart Stores, Inc.; Dr. Richard Andrews; Dr. Theodore Okechuku; Dr. Nicolas Padron; DOES 1 through 100 inclusive	§	Rockwall County - 439th District Court _____ **Judicial District**
	§	**of Rockwall County**
Defendants.		

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

Comes Now the Plaintiff: The County of Rockwall Texas ("Rockwall County" or the "County"), by and through the undersigned attorneys and on behalf of the County Attorney for Rockwall County, and for cause of action would respectfully show the Court and jury as follows:

DISCOVERY CONTROL PLAN

1. Discovery is intended to be conducted under level 3 of Rule 190, TEXAS RULES OF CIVIL PROCEDURE.

CONDITIONS PRECEDENT

2. Plaintiff alleges that all conditions precedent have been performed or have occurred.

RULE 47 STATEMENT OF MONETARY RELIEF SOUGHT

3. Per Rule 47 of the Texas Rules of Civil Procedure, the County states that although the full measure of its damages is still being calculated, its damages caused by Defendants' acts and omissions exceed $1,000,000 but are believed to be less than $100,000,000. Accordingly, at this time in the litigation, Rockwall County states that it is seeking monetary relief for an amount greater than $1,000,000 and less than $100,000,000, the rightful and just amount to be determined by the jury.

PARTIES

4. Plaintiff brings this action for and on behalf of Rockwall County, which provides a wide range of services on behalf of its residents, including, but not limited to, services for families and children, public health, public assistance, law enforcement, and social services, as well as

medical and prescription benefits that the County provides to its employees and retirees.

CORPORATE DEFENDANTS

5. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. Purdue Pharmaceuticals L.P. is licensed by the Food & Drug Safety Licensing Group of the Texas Department of State Health Services ("DSHS") as a manufacturer and/or distributor of prescription drugs in Texas (collectively "Purdue").

6. Purdue manufactures, promotes, sells, and distributes opioids nationally and in Rockwall County, including among them OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

7. Purdue is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, Purdue can be served in accordance with TEX. CIV. PRAC. & REM. CODE §17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079.

8. Cephalon, Inc. ("Cephalon.") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon. Teva Pharmaceutical Industries, Ltd ("Teva, Ltd.") is an Israeli company with its corporate headquarters in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd.

and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011. Teva, Ltd., Teva USA, and Cephalon, Inc. (collectively "Cephalon") work together closely to market and sell Cephalon products in the State of Texas. Teva conducts all sales and marketing activities for Cephalon in the State of Texas through Teva USA and has done so since it's October 2011 acquisition of Cephalon.

9. Cephalon manufactures, promotes, sells, and/or distributes opioids nationally and in Rockwall County, including Actiq and Fentor, for which Cephalon is identified as the drug sponsor and Teva USA is identified as the distributor.

10. Cephalon is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, Cephalon can be served in accordance with TEX. CIV. PRAC. & REM. CODE § 17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079.

11. Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey and is a wholly-owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Otho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief: J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (collectively "Janssen").

12. Janssen manufactures, promotes, sells, and/or distributes opioids nationally and in Rockwall County, including Duragesic, Nucynta and Nucynta ER. These opioid drugs are sold both directly by Janssen and by third party drug distributors. Janssen is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, Janssen can be served in accordance with TEX. CIV. PRAC. & REM. CODE §17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079.

13. Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania (collectively "Endo.").

14. Endo manufactures, promotes, sells, and/or distributes opioids nationally and in Rockwall County, including Opana and Opana ER. Opana ER is reported to have been prescribed up to 50,000 times per day. However, June 8, 2017, the U.S. Food and Drug Administration requested that Endo remove Opana ER from the market based on FDA's concern that the benefits of the drug may no longer outweigh its risks. Endo is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, Endo can be served in accordance with TEX. CIV. PRAC. & REM. CODE § 17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079.

15. Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Knoll Pharmaceutical Company is a wholly-owned subsidiary of Abbott Laboratories and is a New Jersey corporation with its principal place of business in Parsippany, New Jersey (collectively "Abbott").

16. Abbott currently and/or historically manufactures, promotes, sells, and/or distributes opioids nationally and in Rockwall County, including Vicoprofen and Dilaudid. Abbott Laboratories can be served by serving its registered agent as follows: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136.

17. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Allergan Finance, LLC as of October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these Defendants is owned by Allergan PLC, which uses them to market and sell its drugs in Texas. Upon information and belief, Allergan PLC exercised control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit (collectively "Actavis.").

18. Actavis manufactures, promotes, sells, and/or distributes opioids nationally and in Rockwall County, including generic Oxycontin (oxycodone hydrochloride) and Dilaudid (hydromorphone hydrochloride). Allergan Sales is identified as the sponsor and/or entity responsible for the manufacture and/or distribution of the opioid medication Fiorinal with codeine (FDA NDA # 019429). Actavis acquired the rights to another opioid, Kadian (morphine sulfate,

NDA # 020616), from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

19. Actavis is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, Actavis can be served in accordance with TEX. CIV. PRAC. & REM. CODE § 17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079.

20. Actavis has elected to do business in Texas under a license as a domestic drug manufacturer and/or distributor. The entities that are licensed by DSHS to conduct business in Texas as domestic licensees are: Allergan Sales LLC 8301 Mars Dr. Waco, Texas 76712 Allergan USA Inc., 800 Waters Ridge Dr. 100, Lewisville, Texas 75057.

21. Plaintiff alleges that Allergan Sales LLC and Allergan USA Inc. are domiciled in the State of Texas and are proper parties who may be sued under their assumed or common names for enforcing for or against it a substantive right TEX. R. CIV. P. 28. Allergan Sales LLC and Allergan USA Inc. may be served at the above addresses.

22. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures, promotes, sells, and/or distributes opioids nationally and in Rockwall County, including Subsys (fentanyl sublingual spray).

23. Insys can be served by serving its registered agent as follows: CT Corporation System, 1999 Bryan Street, Suite900, Dallas, Texas 75201-3136.

24. Insys has elected to do business in Texas under a license as a domestic drug manufacturer and/or distributor. The entity that is licensed by DSHS to conduct business in Texas as a domestic licensee is: Insys Manufacturing LLC 2700 Oakmont Drive Round Rock, Texas 78665.

25. Plaintiff alleges that Insys Manufacturing LLC is domiciled in the State of Texas and is a proper party who may be sued under its assumed or common name for enforcing for or against it a substantive right. TEX. R. CIV. P. 28. Insys Manufacturing may be served at the above address.

26. McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Rockwall County. The drugs distributed by McKesson include powerful, addictive opioids, such as oxycodone and hydrocodone.

27. McKesson is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, McKesson can be served in accordance with TEX. CIV. PRAC. & REM. CODE § 17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079.

28. McKesson has elected to do business in Texas under a license as a domestic drug manufacturer and/or distributor. There are three "McKesson" entities that are licensed by DSHS to conduct business in Texas as domestic licensees.

29. Plaintiff alleges that McKesson Corporation and McKesson Medical-Surgical Inc. are domiciled in the State of Texas and. are proper parties who may be sued under their assumed common name for enforcing for or against it a substantive right TEX. R. CIV. P. 28. McKesson Corporation and McKesson Medical-Surgical Inc. may be served at the above addresses.

30. Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Rockwall County. The drugs

distributed by Cardinal include powerful, addictive opioids, such as oxycodone and hydrocodone.

31. Cardinal is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, Cardinal can be served in accordance with TEX. CIV. PRAC. & REM. CODE § 17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079.

32. Cardinal has elected to do business in Texas under a license as a domestic drug manufacturer and/or distributor. There are nine "Cardinal" entities that are licensed by DSHS to conduct business in Texas as domestic licensees.

33. Plaintiff alleges that Cardinal Health 110 LLC, Cardinal Health 200 LLC and Cardinal Health 414 LLC are domiciled in the State of Texas and are proper parties who may be sued under their assumed or common name for enforcing for or against it a substantive right Tex. R. Civ. P. Cardinal Health 110 LLC, Cardinal Health 200 LLC, and Cardinal Health 414 LLC may be served at the above addresses.

34. Amerisource Bergen Drug Corporation ("Amerisource") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Rockwall County. The drugs distributed by Amerisource include powerful, addictive opioids, such as oxycodone and hydrocodone.

35. Amerisource is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, Amerisource can be served in accordance with TEX. CIV. PRAC. & REM. CODE § 17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12.079Austin, Texas 78711-2079.

36. Amerisource has elected to do business in Texas under a license as a domestic drug

manufacturer and/or distributor. There are two Amerisource entities that are licensed by DSHS to conduct business in Texas as domestic licensees, including: Amerisource Bergen Drug Corporation 12727 W. Airport Blvd. Sugarland, Texas 77478.

37. Plaintiff alleges that Amerisource Bergen Drug Corporation is domiciled in the State of Texas and is a proper party who may be sued under its assumed or common name for enforcing for or against it a substantive right. TEX. R. CIV. P. 28. Amerisource Bergen Drug Corporation may be served at the above address.

38. Mallinckrodt PLC ("Mallinckrodt") is an Irish public limited company with its corporate headquarters in Staines-Upon-Thames, Surrey, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC, was a wholly-owned subsidiary of Covidien plc. Mallinckrodt Brand Pharmaceuticals is a Delaware Corporation which is wholly owned by Mallinckrodt plc. Defendant SpecGx, LLC, is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. SpecGX currently manufactures and sells certain opioids which were previously manufactured by Mallinckrodt, LLC. Mallinckrodt, plc, Mallinckrodt, LLC, Mallinckrodt Brand Pharmaceuticals, and SpecGx, LLC, are referred to as "Mallinckrodt." Mallinckrodt distributes pharmaceuticals to retail pharmacies and institutional providers across the United States, including Texas and Rockwall County. The drugs distributed by Mallinckrodt include powerful, addictive opioids, such as oxycodone and hydrocodone.

39. Abbvie, Inc. ("Abbvie") is a Delaware corporation with its principal place of

business in North Chicago, Illinois, and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. Knoll Pharmaceutical Company ("Knoll") has been a wholly-owned subsidiary of Abbvie from January 1, 2013. Knoll is a New Jersey corporation with its principal place of business in Parsippany, New Jersey, and may be served through its registered agent for service of process, CT Corporation System, 350 N St. Paul Street, Dallas, Texas 75201.

40. Knoll irresponsibly marketed narcotics, such as Vicodin, through toys and souvenirs and did so to boost the sales of opioids. Taking advantage of the fact that Vicodin was not regulated as a Schedule II controlled substance for many years, and the fact physicians and consumers did not fully appreciate the highly addictive nature of Vicodin, Knoll advertised Vicodin with tag lines such as "The Highest Potency Pain Relief You Can Still Phone In." This tag line came as part and parcel of souvenirs like a "Vicodin" fanny pack and water bottle, both bearing the name of Vicodin, the opioid Knoll was promoting. This irresponsible marketing of a narcotic drug caused doctors and patients to believe Vicodin was safer than it really was, to the detriment of people in Rockwall County. Abbvie began manufacturing, developing, promoting, marketing, and selling the opioid drug, Vicodin, in the U.S. and its opioid business impacts Rockwall County. On information and belief, it continues to do so at the time of filing this pleading.

41. CVS Health ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. CVS is engaging in business in the State of Texas but has not designated or maintained a resident agent for service of process. Therefore, CVS can be served in accordance with TEX. CIV. PRAC. & REM. CODE § 17.042 and § 17.044 by serving the Secretary of the State of Texas, P.O. Box 12079, Austin, Texas 78711-2079. During all relevant times, CVS Health has

sold and continues to sell prescription opioids in and in close proximity to Rockwall County.

42. Walgreens Boots Alliance, Inc., a/k/a Walgreen Co. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois and may be served through its registered agent for service of process, The Prentice-Hall Corporation System, Inc., 211 E. 7th Street, Suite 620, Austin, Texas 78701. At all relevant times, Walgreens has sold and continues to sell prescription opioids in close proximity to Rockwall County.

43. Wal-Mart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Arkansas and may be served through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. At all relevant times, Wal-Mart has sold and continues to sell prescription opioids at locations in and in close proximity to Rockwall County.

44. The foregoing parties are referenced in this petition as the "corporate Defendants" or as the "Defendants."

INDIVIDUAL DEFENDANTS

45. DR. RICHARD ANDREWS is an individual residing in Dallas, Dallas County, Texas. Dr. Andrews was involved in a "pill mill" operation and charged with conspiracy to distribute controlled substances, including oxycodone, to patients in Dallas County and numerous other counties, including Rockwall County.[1] Dr. Andrews agreed to the revocation of his medical license on March 3, 2017 after pleading guilty to two felony charges.[2] Rockwall County is not, however, seeking damages under claims of medical malpractice or medical professional

[1] Department of Justice, "Doctor Who Owned McAllen Medical Clinic in Dallas Pleads Guilty in Pill Mill Case," (January 13, 2017), https://www.justice/usao-ndtx/pr/doctor-who-owned-mcallen-medical-clinic-dallas-pleads-guilty-pill-mill-case.
[2] Texas Medical Board, http://reg.tmb/state/tx/us.com, *last viewed* November 13, 2017.

negligence.

46. DR. THEODORE OKECHUKU is an individual who resided in Dallas, Dallas County, Texas until his sentencing date in October 2015. Dr. Okechuku was involved in a "pill mill" operation and charged with, among other things, conspiracy to distribute controlled substances, including hydrocodone, to patients in Dallas County and other counties, including Rockwall County.[3] Dr. Okechuku lost his medical license as of December 17, 2015.[4] Rockwall County is not, however, seeking damages under claims of medical malpractice or medical professional negligence.

47. DR. NICOLAS PADRON is an individual who resided in Garland, Dallas County, Texas until his sentencing date in March 2014; Dr. Padron was involved in a "pill mill" operation and charged with conspiracy to distribute controlled substances, including hydrocodone, to patients in Dallas County and other counties, including Rockwall County.[5] Dr. Padron agreed to the revocation of his medical license on October 1, 2012 in lieu of further disciplinary proceedings after pleading guilty to one charge of conspiracy to commit healthcare fraud.[6] Rockwall County is not, however, seeking damages under claims of medical malpractice or medical professional negligence.

48. The County lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. The County will amend this Petition to show their

[3] "Trial for Dallas Doctor Accused of Running Pill Mill," (October 6, 2015), http://www.zenlawfirm.com/Law-Blog/2015/October/Trial-for-Dallas-Doctor-Accused-of-Running-Pill-.aspx.
[4] Texas Medical Board, http://reg.tmb/state/tx/us.com, *last viewed* November 13, 2017.
[5] "Garland Doctor, other 'Dealers' Sentenced in Dallas 'Pill Mill' Case," (October 29, 2014), http://starlocalmedia.com/rowlettlakeshoretimes/garland-doctor-other-d...llas-pill-mill-case/article_d53be5fc-5fbc-11e4-9186-af37156f06a3.html.
[6] Texas Medical Board, http://reg.tmb/state/tx/us.com, *last viewed* November 13, 2017.

true names and capacities if and when they are ascertained. Rockwall County is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE has engaged in conduct that contributed to cause events and occurrences alleged in this Petition and, as such, shares liability for at least some part of the relief sought herein.

49. Dr. Richard Andrews, Dr. Theodore Okechuku, and Dr. Nicholas Padron shall henceforth be collectively referred to as the "Individual Defendants."

STANDING

50. Rockwall County has standing to bring this lawsuit because it has suffered an injury-in-fact caused by Defendants' misconduct, and that harm can be redressed through this action. The Commissioner's Court of Rockwall County, in the exercise of its power and authority over County business, expressly and formally has authorized the filing of this petition and the pursuit of the legal remedies raised herein, and does so in the name of and for the benefit of Rockwall County. Having decided that it was necessary to pursue these claims to protect the County's interests, the County Commissioner's Court, on behalf of Rockwall County, hired outside counsel to handle the litigation. The contract governing the County's representation in this litigation was approved by the Texas Comptroller of Public Accounts pursuant to Tex. Gov't Code § 403.0305.

33. Defendants' misconduct has placed an unreasonable burden on Rockwall County's resources and ability to provide the public services and employee benefits it is obligated to and/or has authority to provide to its residents and employees. Rockwall County has the statutory duty and/or authority to provide public safety and health services, including, but not limited to, the following:

- Supporting paupers;[7]
- Providing county jails;[8]
- Providing health care in county jails;[9]
- Providing fire protection;[10]
- Enforcing drug laws;[11]
- Contracting with drug centers;[12]
- Commissioning drug education and counseling programs;[13] and
- Paying county and precinct officers and employee compensation, office and travel expenses, and any other allowances.[14]

34. Defendants' misconduct – including Manufacturing Defendants' calculated marketing campaign of misinformation to physicians and patients, and Distributor Defendants' disbursement and distribution of prescription opioids even though suspicion for diversionary purposes existed – caused the damages to the County. They misled physicians into overprescribing opioids, which directly created the need for dramatically increased public services. The County relied on these misrepresentations in paying for its employees' healthcare costs causing the County to incur increased healthcare costs for its own employees.

35. The harm caused by Defendants' misconduct can be redressed by the Court in this action. Defendants should be enjoined from continuing to manufacture, distribute, and sell opioids in Rockwall County without a medical purpose and without educating physicians and patients

[7] Tex. Local Gov't Code § 81.027.
[8] *Id.* at § 351.001.
[9] *Id.* at § 351.045.
[10] *Id.* at § 352.001.
[11] *Id.* at § 370.003.
[12] Tex. Health & Safety Code at § 464.032.
[13] *Id.* at § 465.001
[14] Tex. Local Gov't Code § 152.011.

about the actual risks and benefits of its drugs. Furthermore, Defendants should compensate Rockwall County for the funds it has expended and continues to expend for medical insurance claims for opioids that were not medically necessary, as well as increased costs of social services, health systems, law enforcement, the judicial system, and treatment facilities, and the increased costs and loss of revenue caused by the plague of crippling addiction.

VENUE AND JURISDICTION

36. Venue is proper in Rockwall County because all or a substantial part of the events or omissions giving rise to this claim occurred in Rockwall County. TEX. CIV. PRAC. & REM. CODE §15.002(a)(2). This Court has subject-matter jurisdiction over this matter because Plaintiff's damages are in excess of the minimal jurisdictional limits of this Court. TEX. GOVT. CODE §24.007(b).

35. This Court has general jurisdiction over the Individual Defendants as they are Texas residents. This Court also has specific jurisdiction over all Defendants as their activities were directed toward Texas, and injuries complained of herein resulted from their activities. *Guardian Royal Exchange Assur., Ltd. v. English China Clays, P.L.C.*, 815 S.W.2d 223, 227 (Tex. 1991). Each Defendant has a substantial connection with Texas and the requisite minimum contacts with Texas necessary to constitutionally permit the Court to exercise jurisdiction. *See id.* at 226.

36. There is no federal subject matter jurisdiction over this action. There is no federal subject matter jurisdiction pursuant to 28 U.S.C. Section 1332(a) because the Plaintiff is a citizen of the State of Texas and defendants are citizens of the State of Texas, thereby destroying complete diversity. There is no federal subject matter jurisdiction pursuant to 28 U.S.C. Section 1332(d) because the Plaintiff does not bring this case as a class action or as a mass action. The County expressly and permanently does not, and disavows, any proposal to try its claims with 99 other

persons.

37. There is no federal subject matter jurisdiction pursuant to 28 U.S.C. Section 1331 because no claim in this petition arises under the Constitution, laws, or treaties of the United States.

38. Moreover, even assuming there is a federal question, which is denied, no such federal question is substantial to the federal system as a whole. *See Gunn v. Minton*, 568 U.S. 251 (2013). To the extent any federal proceeding is allegedly discussed or referenced directly or indirectly in this petition, these pleadings do not state any federal claim or raise any federal question but rather are factual allegations showing Defendants' *mens rea* and the course of Defendants' malfeasance as a factual matter. No federal question is substantial, is raised, or is necessarily adjudicated here because the County exclusively is relying on state law rather than on any federal law, regulation or standard. The statements in this paragraph are controlling notwithstanding anything allegedly to the contrary in this petition.

39. There is no removal jurisdiction under 28 U.S.C. Section 1442. The County makes no claim, and expressly disavows any alleged claim, against or directed to the United States or any agency thereof or any officer (or any person acting under that officer) of the United States or any agency thereof, in an official or individual capacity, for or relating to any act under color of such office; including without limitation, the County denies seeking, and expressly disavows, any recovery arising from McKesson Corporation's federal contract to supply prescription medication. The statements in this paragraph are controlling notwithstanding anything allegedly to the contrary in this petition.

FACTUAL ALLEGATIONS

40. Before the 1990s, generally accepted standards of medical practice dictated that opioids should be used only for short-term acute pain – pain relating to recovery from surgery or

for cancer or palliative (end-of-life) care. Using opioids for chronic pain was discouraged or even prohibited because there was a lack of evidence that opioids improved patients' ability to overcome pain and function. Instead, the evidence demonstrated that patients developed tolerance to opioids over time, which increased the risk of addiction and other side effects.

41. After the 1990s, Defendants dramatically changed doctors' views regarding opioids through a well-funded deceptive marketing scheme. Defendants were so successful that, according to the National Safety Council, 74% of ***all*** doctors prescribe opioids for chronic back pain and 55% prescribe opioids for dental pain, "neither of which is appropriate in most cases."[15] And 99% of doctors are prescribing them for longer than the three-day recommended period as recommended by the CDC.[16] Twenty-three percent prescribe at least a month's worth of opioids and evidence shows that just 30 days of usage can cause brain damage.[17]

42. Each Defendant used direct marketing and unbranded advertising (*i.e.*, advertising that promotes opioid use generally but does not name a specific opioid) disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use. Defendants advocated the widespread use of opioids for chronic pain even though it contravened the "cardinal principles of medical intervention – that there be compelling evidence of the benefit of a therapy prior to its large-scale use."

A. Defendants Used Multiple Avenues to Disseminate their False and Deceptive Statements about Opioids.

43. Defendants spread their false and deceptive statements by (1) marketing their

[15] National Safety Council, *NSC Poll: 99% of Doctors Prescribe Highly-Addictive Opioids Longer than CDC Recommends*, 2017 (The NSC was founded in 1913 and chartered by Congress and is a non-profit organization whose mission is to save lives by preventing injuries and deaths at work, in homes, and in the communities through leadership, research, education, and advocacy).
[16] *Id.*
[17] *Id.*

branded opioids directly to doctors treating patients residing in Rockwall County and the Rockwall County patients themselves and (2) deploying so-called unbiased and independent third parties to Rockwall County.

1. Defendants Spread and Continue to Spread Their False and Deceptive Statements Through Direct Marketing of Their Branded Opioids.

44. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturing Defendant conducted advertising campaigns touting the purported benefits of their branded drugs. For example, Purdue spent $200 million promoting and marketing OxyContin in various forms. Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001, including $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

45. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like a construction worker and chef, implying that the drug would provide long-term pain-relief and functional improvement.

46. Purdue also ran a series of ads, called "pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Second, each Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs.

47. Defendants devoted massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $154 million on detailing branded opioids to doctors, including $108

million by Purdue, $34 million by Janssen, and $10 million by Endo.

48. Defendants sent their sales representatives to prescribers based on their specialties and prescribing habits obtained from sales data through IMS Health. Defendants used this data to monitor, and thereby target, specific physicians through the initial and renewal prescribing rates. To ensure that their sales representatives were properly incentivized, Defendants motivated them through bonuses. In 2001, Purdue paid $20 million in "sales incentive bonuses" to its sales representatives.

49. Defendants also utilized "influence mapping" to use decile rankings or similar breakdowns to identify high-volume prescribers. The underlying strategy was that detailers would have the biggest sales impact on high-volume prescribers. For example, Endo identified prescribers representing 30% of its nationwide sales volume and planned sales visits three times per month to these physicians. These detailers visited physicians across the nation, including physicians in Rockwall County. Defendants also had access to data from IMS Health, which provides Defendants specific details about which medications physicians prescribe and how frequently they do so. This data was collected from more than 50% of the pharmacies in the United States, which would inform Defendants which doctors to target to convince them to prescribe more opioids or to start prescribing opioids instead of the medications they had been prescribing.

50. Another manner in which Defendants expanded their sales was to target prescribers in individual zip codes and local boundaries. Defendants would send a detailer based on ease of in-person access and the likelihood of convincing the physician to prescribe a higher number of opioids and at higher doses.

51. As part and parcel of their detailing of opioids to physicians, Purdue trained its sales representatives to inform physicians that the risk of addiction was "less than one percent" even

though studies demonstrated that there was a high incidence of drug abuse associated with prescription opioid use for chronic pain.

52. As Defendants' marketing efforts grew, they targeted nurse practitioners and physician assistants who, a 2012 Endo business plan noted, were "share acquisition" opportunities because they were more responsive than physicians to details and wrote most of their prescriptions without a physician consult.

53. Studies demonstrate that visits from sales representatives influence the prescribing practices of residents and physicians by curtailing the prescription of generic drugs and rapidly expanding the prescription of new drugs, such as opioids for chronic pain. In a population-based county-level analysis of drug company marketing of prescription opioids – a study which included ***all*** U.S. counties – the marketing of opioid products to physicians was associated with both increased opioid prescribing and elevated mortality from overdoses.[18]

54. Defendants also paid doctors to serve on speakers' bureaus, to attend programs, and for meals. In 2017, Dr. Hadland identified some of these payments from pharmaceutical companies to physicians prescribing opioids. It was the first time "industry payments to physicians related to opioid marketing" could be collated because of the "Open Payments program database" authorized under the "Physician Payments Sunshine Act." Dr. Hadland explained that it was the first large-scale examination of these payments.

55. One statistic Dr. Hadland gleaned from the data is that nearly 1 in 5 family physicians in 2013, out of 108,971 active family physicians, received an opioid-related payment. After culling through the Open Payments program database, Dr. Hadland concluded that

[18] Hadland, S.E., Rivera-Aguirre, A., Marshall, B.D.L., Cerdá, M. (Jan. 2019). Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality From Opioid-Related Overdoses." *The Journal of American Medical Association (JAMA) Network Open.* DOI:10.1001/jamanetworkopen.2018.6007

"[f]inancial transfers" from pharmaceutical companies to physicians prescribing opioids "were substantial and widespread and may be increasing in number and value."[19]

56. Some of the financial transfers most likely involved speaker programs, which provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

57. Defendants employed the same marketing plans, strategies, and messages in and around Rockwall County, Texas as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

2. Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Deceptive Statements about the Risks and Benefits of Opioids.

58. Defendants also deceptively marketed opioids in and around Rockwall County through unbranded advertising. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third

[19] *Id.* at 1495.

parties and acted in concert with them to falsely and misleadingly promote opioids for treating chronic pain. Unbranded advertising also avoided regulatory scrutiny because Defendants did not have to submit it to the FDA, and therefore it was not reviewed by the FDA. But it is illegal for a drug company to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy that clearly cannot be supported by the results of the study. Moreover, a drug company cannot compare or suggest that its drug is safer or more effective than another drug when it has not been demonstrated to be safer or more effective in such particular by substantial evidence of substantial clinical experience. It is therefore Defendants' responsibility to ensure that not only is its label accurate and complete, but that any and all materials they distribute is accurate and complete.

59. Defendants' deceptive unbranded marketing often contradicted their branded materials. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**
"People who take opioids **as prescribed usually do not become addicted**."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

60. Drug companies that make, market, and distribute opioids are generally subject to rules requiring truthful marketing of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.

61. This framework ensures that drug companies, which are best suited to understand the properties and effect of their drugs, bear the responsibility of providing accurate information so that prescribers and users can assess the risks and benefits of the drugs.

62. Defendants did not follow this framework in assisting, creating, and/or distributing third-party publications that included warnings and instructions either mandated by the FDA-required drug labels or that described the risks and benefits known to Defendants. The publications either failed to disclose the risk of addiction and misuse or affirmatively denied the risk of addiction. The publications also "appeared" to be independent third-party materials that had the effect of carrying more weight and credibility to convince physicians that opioids were safe for chronic pain.

a. Defendants Utilized Treatment Guidelines to Promote their Deception.

63. Defendants used treatment guidelines to normalize the use of opioids for chronic pain. Doctors, especially general practitioners and family doctors, rely upon treatment guidelines when faced with patients complaining of chronic pain. Scientific literature references treatment guidelines in making its conclusions and third-party payers use treatment guidelines to determine coverage. Even Endo's internal documents indicate that sales representatives discussed treatment guidelines with doctors during individual sales visits.

1. The FSMB Wrote or Sponsored Misleading and Deceptive Guidelines.

64. Headquartered in Euless, Texas, the Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline doctors. The FSMB finances opioid and pain-specific programs through grants from Defendants.

65. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which was produced in collaboration with pharmaceutical companies. The FSMB guidelines instructed that opioids were "essential" for the treatment of chronic pain, even as a first prescription option.

66. A book adapted from the 2007 FSMB guidelines, *Responsible Opioid Prescribing: A Physician's Guide* ("*Opioid Prescribing*"), released March 1, 2009 makes these same claims.[20] *Opioid Prescribing* was supported by a consortium of pharmaceutical companies and Front Groups with an interest in ensuring that "effective" pain management included the use of opioids.

67. The author of *Opioid Prescribing*, Scott Fishman, M.D., chaired the board of the American Pain Foundation and served as president of the American Academy of Pain Medicine. *Opioid Prescribing* was sponsored by the Alliance of State Pain Initiatives, Federation of State Medical Boards, and the University of Wisconsin School of Medicine and Public Health.

68. Dr. Fishman was a paid consultant to Cephalon and Eli Lilly. Dr. Fishman was also a paid consultant, on the Speakers' Bureau, and part of the research support for Endo, Merck, Janssen, Pfizer and Purdue.[21]

69. *Opioid Prescribing* was designed for continued medical education ("CME") in which a physician had to read the book, complete questions, and fulfill administrative steps to receive 7.5 hours of credit. The first page of *Opioid Prescribing* specifically states that opioids are the "drugs of choice" and "essential in the treatment of persons with chronic non-cancer pain" and that the CME will inform physicians about the laws and regulations governing the prescribing of opioids for pain control.[22] It also specifically teaches physicians how to protect their practices from

[20] Scott M. Fishman, M.D., *Responsible Opioid Prescribing, A Physician's Guide*, FSMB Foundation, Waterford Life Sciences, 2009.
[21] *Id.*
[22] *Id.*

unwarranted federal scrutiny.[23]

70. *Opioid Prescribing* marketed "[o]pioid analgesics" as the "drugs of choice for the management of moderate to severe pain… [which] may be ***essential*** in the treatment of persons with chronic non-cancer pain."[24] The goal was to "change patient care, medical knowledge, practice-based learning, interpersonal and communication skills, and professionalism…."[25] The argument was that opioids were "underutilized" despite their "effectiveness."[26] The truth, known to Dr. Fishman and Defendants herein, was that using opioids "for other than legitimate medical purposes pose[d] a threat to the individual and society," posed high risks for overdose and addiction, and remained unproven as safe and effective for the long-term treatment of non-cancer pain.[27]

71. It was even conveyed to doctors that undertreating pain would be officially disciplined whereas doctors prescribing opioids for chronic pain would not be disciplined. *Opioid Prescribing* described a case in which a physician was sued for "elder abuse" and the jury awarded $1.5 million to the plaintiff as an example of a physician that had been "successfully sued for not treating pain aggressively."[28] *Opioid Prescribing* cautioned that "these legal precedents sound a warning that there are risks associated with under-treating."[29] In actuality, it was a threat that doctors would be punished if they *failed* to prescribe opioids to patients who complained about pain. That teaching has held true given that according to the National Safety Council, 67% of doctors prescribe opioids, in part, based on a patient's expectations.[30] Moreover, approximately

[23] Fishman, *supra.*
[24] *Id.* at i.
[25] *Id.*
[26] Fishman, *supra.*
[27] *Id.* at 6, 9.
[28] *Id.* at 28.
[29] Fishman, *supra.*
[30] National Safety Council, *supra*.

74% of doctors incorrectly believe morphine and oxycodone are the most effective ways to treat pain even though research shows that over-the-counter medications such as ibuprofen and acetaminophen are the most effective pain relief for acute pain.[31]

72. Defendants also allayed any concerns doctors may have about patients exhibiting addictive behavior by highlighting the now debunked myth of "pseudoaddiction." Dr. Fishman described pseudoaddiction as a sign that patients were receiving an inadequate dose to obtain pain relief, not as a sign that the patient was, in truth, exhibiting drug-seeking or addictive behavior.[32]

73. *Opioid Prescribing* misinformed physicians that the following signs were evidence of "pseudoaddiction" and *not* drug seeking behavior or signs of addiction so long as prescribing additional opioids resolves the pain:

- Requesting analgesics by name;
- Demanding or manipulative behavior,
- Clock watching;
- Taking opioid drugs for an extended period;
- Obtaining opioid drugs from more than one physician; and
- Hoarding opioids.[33]

89. Indeed, the types of behaviors that Dr. Fishman posed as "MORE indicative of addiction" included:

- Stealing money to obtain drugs;
- Performing sex for drugs;
- Stealing drugs from others;

[31] Fishman, *supra.*
[32] Fishman, *supra* at 62.
[33] *Id.*

- Prostituting others for money to obtain drugs;
- Prescription forgery; and
- Selling prescription drugs.[34]

90. Certainly, by the time a patient is performing sex for drugs, the patient has long been addicted and exhibited addictive behavior that was ignored by physicians at the explicit direction of Defendants. This conclusion is supported by the American Psychiatric Association.

91. In the DSM-IV, addiction is "manifested" by three (or more) of the following in a 12-month period, including:

a) Tolerance described as:

A need for markedly increased amounts of the substance to achieve intoxication or the desired effect

or

Markedly diminished effect with continued use of the same amount of the substance;

b) Withdrawal manifested by:

The characteristic withdrawal syndrome for the substance

or

The same (or closely related) substance is taken to relieve or avoid withdrawal symptoms;

c) The substance is taken in larger amounts or over a longer period than intended; and

d) Spending a great deal of time to obtain the substance, such as visiting multiple doctors or driving long distances.[35]

[34] *Id.* at 63.
[35] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Ed., Washington, D.C., American Psychiatric Assoc., 2000.

92. According to Defendants, as seen in *Opioid Prescribing* and other publications, signs of addiction as defined by the American Psychiatric Association allegedly are not signs of addiction, but of pseudoaddiction that justifies taking *more* opioids for a longer period of time.

93. The reason not to discontinue the use of opioids – indeed, the foundation upon which Defendants built their opioid empire – was "the undertreatment of pain."[36] *Opioid Prescribing* claimed the undertreatment of pain has "been recognized as a public health crisis for decades. The cost of human suffering is immeasurable. Turning away patients in pain simply is not an option."[37] However, according to Dr. Donald Treater, medical advisor at The National Safety Council: "Opioids do not kill pain; they kill people."[38]

94. *Opioid Prescribing* acknowledged that by 2005, more than 10 million Americans were abusing prescription drugs, which is more than the combined number of people abusing cocaine, heroin, hallucinogens, and inhalants combined. It also acknowledged that prescription opioids are associated with more overdose deaths than cocaine and heroin combined.[39] Yet the book then cautioned that the "undertreatment" of non-cancer pain was a public health crisis of equal importance that justified more opioid prescribing.

95. Under the guise of addressing "legitimate cause of undertreated pain" that "patients and advocates have been pushing to address,"[40] Manufacturing Defendants tailored opioid marketing campaigns to affect children and the elderly. The Defendants made significant efforts to promote more opioid prescribing for "untreated or undertreated pain in children, older patients,

[36] Fishman, *supra,* at 105.
[37] *Id.*; *see also id.* at 80 (stating that efforts have been made to reduce the undertreatment or non-treatment of pain in children, the elderly, and in other vulnerable patient populations).
[38] National Safety Council, *supra*.
[39] *Id.*; *Prescribing Opioids* even recognized that "[b]ehind these figures lie millions of individual stories of personal tragedy: untimely death, fractures families, shattered dreams and wasted lives." *Id.* at 7.
[40] *Id.* at 8.

and in all other vulnerable patient populations."[41]

96. Defendants also taught physicians that "[p]ain is what the patient says it is" and that a physician "cannot measure or even confirm the pain that a patient is experiencing."[42] As such, "pain remains an untestable hypothesis."[43] Furthermore, "[p]atients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient."[44] All in all, opioids would cure the "pain epidemic" facing Americans. And yet, chronic pain continues to be a problem facing Americans, as well as an opioid epidemic of addiction and death.

97. A total of 200,000 copies of *Opioid Prescribing,* which Dr. Fisherman wrote for the FSMB, has been delivered to U.S. prescribers through 20 state medical boards in all 50 states, including Texas. The FSMB earned approximately $250,000 from the sale. The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

98. The guidelines for *Opioid Prescribing* were posted online for use and reliance by physicians throughout America, including but not limited to, those servicing patients in Rockwall County. State medical boards even encouraged physicians to buy the book and participate in the CME. The North Carolina Medical Board stated on its website that *Opioid Prescribing* "has been ***widely used and supported*** in the medical and regulatory communities as the leading continuing medical education (CME) activity for prescribers of opioid medications."[45] The website then informs physicians that a CME accompanies the book and directs them to the book and how to

[41] Fishman, *supra*, at 8.
[42] *See id.* at 14.
[43] *Id.* at 13.
[44] *Id.* at 9.
[45] North Carolina Medical Board, *FSMB Foundation Publishes Second Edition of Prescribing Book*, Forum Newsletter, July 31, 2012; *see also* University of Wisconsin School of Medicine and Public Health, Federation of State Medical Boards, *Responsible Opioid Prescribing – Book Helps Physicians Reduce Risk of Opioid Diversion and Abuse*, April 1, 2009 (describing the book and CME activity).

claim the CME. The FSMB also hosted free CMEs in Texas, including Houston, Dallas, and Austin, related to extended-release and long-acting opioids.[46] The CME taught physicians the "safe and responsible prescribing of opioid medications and [was] aimed at improving prescriber training and counseling for patients while providing more thorough information on extended-release or long-acting (ER/LA) opioid products on the market."[47]

99. The impact of *Opioid Prescribing* was even studied through a survey sent to 12,666 licensed Georgia physicians six weeks after receiving the book.[48] The lead author was a member of FSMB.[49] A total of 508 physicians completed the online survey and of those, 82.1% rated the book either "very good" or "good" for improving care for their patients in pain.[50] Almost one-third (32.2%) claimed that they intended to make changes to their practice after reading the book.[51] Of note, 42.8% of solo practitioners and 41.6% of primary care providers were more likely to make changes to their practice than doctors in other areas.[52] Of the respondents, 57.7% said that the book was better than others with regard to prescribing opioids and on pain management.[53]

100. *Opioid Prescribing* was therefore an effective tool that impacted specific doctors and their prescribing practices, as concluded by the study. Specifically, the study provided "insight into which physician population would be the most receptive to the type of information presented in Dr. Fishman's book" and that population was to "first target [] solo and primary care physicians."[54] Defendants found out that their educational efforts "significantly altered

[46] Texas Medical Board, *Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy*, www.tmb.state.tx.us.
[47] *Id.*
[48] A. Young, *Physician Survey Examining the Impact of an Educational Tool for Responsible Opioid Prescribing*, J. Opioid Management, Mar-Apr. 2012.
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*

prescription practices."[55]

2. The Joint Commission Also Spread Deceptive Information.

101. The Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") is a United States-based non-profit, tax-exempt organization that "accredits and certifies nearly 21,000 health care organizations and programs in the United States."[56] A majority of state governments recognize accreditation from the Joint Commission as a condition of licensure and for receiving Medicaid and Medicare reimbursements.[57]

102. According to the JCAHO, it "continuously improve[s] health care for the public" and inspires health care organizations "to excel in providing safe and effective care of the highest quality and value."[58] The JCAHO is not independent, but has been influenced by Manufacturing Defendants and those Defendants used the JCAHO as a marketing shill to spread the misleading message that opioids are non-addictive and safe as a first-line analgesic to treat any complaint of pain.

103. In 2000, the JCAHO published *Pain Assessment and Management: An Organizational Approach* ("*Pain Assessment"*), which was paid for by Purdue and reviewed by June L. Dahl, Ph.D., who had worked for Endo and Purdue.[59]

104. The JCAHO mission statement on the inside cover page of the book explains that it aspires "to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support the performance

[55] Young, *supra.*
[56] www.jointcommission.org.
[57] Anthony Anonimo, *Poppy Seed. Revealing the Roots of the Opioid Epidemic,* Trinity Mother Frances Health System, 2017, at 65.
[58] *Id.*
[59] Joint Commission on Accreditation of Healthcare Organizations, *Pain Assessment and Management*, 2000.

improvement in health care organizations."[60] One of its big achievements, however, is its endorsements of new pain management standards that underscored Defendants' fraudulent message.

105. JCAHO, with the help of the American Pain Society ("APS"), a Front Group, loosened pain management standards thereby allowing doctors to prescribe opioids for any complaint of pain. To that end, "[t]he Joint Commission recognize[d] pain as a major, yet largely avoidable, problem…. [and] has expanded the scope of its pain management standards, which have been endorsed by the American Pain Society (APS), ***to cover all pain scenarios in accredited health care organizations rather than limiting the scope to end-of-life care***."[61] On January 1, 2001, Texas incorporated JCAHO pain management standards for hospital and healthcare group accreditation.[62] The Texas Medical Association advertises that *Pain Assessment* "provides practical help in integrating pain assessment and management into organizational systems…."[63]

106. *Pain Assessment* established the cornerstone of Defendants' message that "all pain scenarios" should be included in pain management practices.[64] It explained that "[p]ain is the most common reason individuals seek medical attention. According to the American Pain Society (APS), 50 million Americans are partially or totally disabled by pain."[65] "The conclusion? Pain is undertreated – despite the availability of effective pharmacologic and nonpharmacologic therapies. Why?"[66]

107. The answer is on the first page of *Pain Assessment*. Allegedly, there is a chronic

[60] *Pain Assessment and Management, supra.*
[61] *Id.* (emphasis added).
[62] Texas Medical Association, *JCAHO Pain Management Services*, *available at* https://www.texmed.org/Template.aspx?id=2389&terms=The%20war%20on%20pain.
[63] *Pain Assessment*, *supra*.
[64] *Pain Assessment*, *supra,* at p. 1.
[65] *Id.*
[66] *Id.*

pain epidemic and, allegedly, chronic pain is undertreated. Chronic pain allegedly can be managed and even cured with opioids, which are safe and effective, according to *Pain Assessment*. And the JCAHO encouraged organizations to establish standards for recording and responding to patient pain reports and monitoring staff performance and compliance with those standards, so that a physician who did not agree with the JCAHO standards faced the specter of poor performance evaluations.[67]

108. According to *Pain Assessment*, the reasons healthcare professionals had not used opioids previously included: (1) inadequate knowledge of opioids pharmacology and pain therapy, (2) poor pain assessment practices, (3) unfounded concerns about regulatory oversight, and (4) fear of opioids' side effects of opioids such as tolerance and addiction.[68]

109. *Pain Assessment* asserted that few practitioners received adequate training in pain management in medical school or during their residency resulting in the failure to prescribe opioids or nonsteroidal anti-inflammatory drugs (NSAIDS) on a regular basis leaving patients without pain relief.[69] "[Many] health care professionals lack the knowledge and skills to manage pain effectively, and they fear the effects of treatment."[70] Too few health care systems make pain management a priority, according to the misinformation campaign.[71] Some clinicians allegedly had "inaccurate and exaggerated concerns about addiction, tolerance, respiratory depression, and other opioid side effects, which lead them to be extremely cautious about the use of drugs."[72] Instead of expanding upon and explaining the risks of opioids, *Pain Assessment* falsely states: "***This attitude prevails despite the fact there is no evidence that addiction is a signification issue when persons***

[67] *Pain Assessment*, *supra* at 41-42.
[68] *Id.*
[69] *Id.*
[70] *Id.* at 3.
[71] *Id.* at 1.
[72] *Pain Assessment*, *supra*, at 4.

are given opioids for pain control."[73] That claim of insignificant addiction risk was false when made and remains false today. Yet it worked as intended to mislead treating doctors, medical staff, and patients into believing opioids could and should be utilized more often. Indeed, 74% of doctors "incorrectly believe morphine and oxycodone" are the "most effective ways to treat pain" even though research shows that over-the-counter pain relievers are the most effective for acute pain.[74] Even worse, 20% of doctors prescribing opioids prescribed at least a month's worth, even though the evidence shows that "30-day use causes brain changes."[75]

110. Patients also contributed to the pain epidemic by their reluctance to report their pain and to take medications,[76] according to *Pain Assessment.* Doctors were instructed to engage patients in conversations about their pain before prescribing opioids by: (1) asking for pain relief when the pain begins; (2) helping the doctor or nurse assess the pain; and (3) telling the doctor or nurse if the pain is not relieved.[77] Doctors were taught that "[t]he single most reliable indicator of the existence and intensity of pain is the individual's self-report."[78] Indeed, the individual's self-report was to be the ***primary*** source of information for the doctor and deemed more reliable than the observations of others.[79]

111. The bombardment of information, instruction, books, pamphlets, seminars, ads, and marketing regarding this "pain epidemic" was so successful that pain has been included as the "fifth vital sign" to be recorded along with the individual's temperature, pulse, respiration, and blood pressure.[80] This strategy was first pitched by the APS to ensure that pain management gained

[73] *Id.*(emphasis added).
[74] National Safety Council, *supra.*
[75] *Id.*
[76] *Pain Assessment*, *supra*, at 4.
[77] *Id.* at 8.
[78] *Id.* at 13.
[79] *Id.*
[80] *Pain Assessment, supra*, at 20.

acceptance in the medical community, which it did.[81]

112. Beginning in 1999, the Veteran's Health Administration began routinely assessing pain as the fifth vital sign in every individual.[82] And according to *Pain Assessment*, the research showed that "when pain assessment information is included in clinical charts, those individuals' analgesics [meaning opioids] are more likely to be increased."[83] In other words, including pain as a fifth element results in not only the prescribing of more opioids, it results in the prescribing of higher doses of opioids.

113. *Pain Assessment* also framed the role of key opinion leaders ("KOLs") as purportedly trustworthy people "to evaluate new clinical information, assess new practices, and then determine their value within the context of the local setting."[84] Doctors were expected to accept KOLs' opinions even though KOLs are ***not*** "necessarily innovators or authority figures."[85] KOLs convinced practitioners that their current chronic pain treatment was "outdated, inappropriate, unsupported by research evidence, or no longer accepted by colleagues."[86]

114. In addition, "expert" leaders influenced and implemented protocols with individuals or small groups.[87] These "academic strategies" included "conducting interviews to determine baseline knowledge, stimulating active participation during educational sessions, using concise graphic educational materials, and highlighting or replicating essential messages."[88] Academic detailing was modeled after pharmaceutical detailing practices in which representatives visited physicians to talk about specific medicines, just as Defendants' representatives met with

[81] *See id.* 20-21.
[82] *Id.* at 21.
[83] *Pain Assessment*, *supra.*
[84] *Id.* at p. 24.
[85] *Id.*
[86] *Id.* at 25.
[87] *Id.*
[88] *Pain Assessment*, *supra*, at 25.

physicians to talk about opioids.[89] Simply put, *Pain Assessment* was a part of a marketing campaign to plow ground for Manufacturing Defendants to sell more opioids, and the book set forth sophisticated, multi-layered marketing strategies that were most effective in executing the campaign.

115. If a doctor was not available to prescribe opioids, a nurse would suffice. A nurse specializing in oncology, surgery, critical care, or a nurse anesthetist, as well as a clinical pharmacist, can "serv[e] as role models, provid[e] pain management education and consultation, and act[s] as agents of change."[90] These educational efforts "significantly altered prescription practices."[91]

116. To succeed in prescribing opioids for chronic pain, Defendants had to create a market for chronic pain. To do so, Defendants literally encouraged patients not to tolerate pain and to fear pain *more* than opioid addiction.[92] Physicians and their staff were encouraged to educate their patients about "effective pain management," which included the use of opioids.[93] *Pain Assessment* explained research that showed Americans would rather bear pain because they were afraid of "addiction, dependence on drugs, and tolerance to medications," which affected not only the patient's willingness to report pain, but to use adequate amount of opioids to control the pain.[94] A patient's reluctance to take opioids out of fear they would not function normally allegedly meant that the problem was "underreported" and the pain went "untreated."[95]

117. Consequently, the answer was to inform and educate the patient that unrelieved

[89] *Id.*
[90] *Pain Assessment, supra.*
[91] *Id.*
[92] *Id.* at 33.
[93] *Id.*
[94] *Id.*
[95] *Pain Assessment, supra*, at 33.

pain is harmful and that he or she should communicate pain.[96] *Pain Assessment* instructed the use of pain assessment instruments, including pain intensity scales, to describe the nature of the pain and stressed that the "most reliable indicator of pain" was the individual's self-report.[97] Once the patient reported the pain, the physicians and staff were taught to tell the patient about opioids, explain that opioids were safe and effective, describe the name, dosage, and duration of the opioid therapy, and explain the risk of pain versus the importance of pain management.[98]

118. To ensure that patients self-reported pain prior to hospital visits, *Pain Assessment* encouraged health care systems to provide individuals and families with pain management information ***prior*** to being admitted.[99] And health care systems were told to leave individuals and family members with audio and videotapes to watch and listen to about the "importance" of "pain relief" so that they truly understood the message – that is, if you have "pain," tell us and we will provide opioids.

119. The JCAHO was not independent and did not improve the safety or quality of healthcare. Instead it was hijacked by Defendants to standardize pain management criteria that required the use of opioids for chronic pain. The JCAHO was merely a pawn in the Manufacturing Defendants' larger game.

120. Like other books and pamphlets used by Defendants to spread their "message," *Pain Assessment* was distributed throughout the nation and in Texas.

b. Key Opinion Leaders (KOLs) were another Means of Disseminating False Information.

121. Defendants also sponsored KOLs, a small circle of doctors who, upon information

[96] *Id.* at 35.
[97] *Id.*
[98] *Pain Assessment, supra.*
[99] *Id.* at 36.

and belief, were selected, funded, and elevated by Defendants because they publicly supported dispensing opioids more widely and indiscriminately.

122. Defendants paid KOLs to serve as consultants or to appear on their advisory boards and to give talks or present CMEs, and Defendants' support helped these KOLs become respected industry putative experts. As they rose to prominence, these KOLs promoted the benefits of opioids to treat chronic non-cancer pain, repaying Defendants by advancing their marketing goals.

123. KOLs wrote articles and books, gave speeches, and taught CMEs to promote the utilization of opioids to treat moderate non-cancer pain. Defendants created opportunities for KOLs to participate in "studies" and write papers for the purpose of advancing the Manufacturing Defendants' marketing theme: opioids should be dispensed regularly and perpetually to treat a broad array of pain complaints.

124. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage using opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs.

125. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for using opioids for chronic pain.

126. Different Defendants utilized many of the same KOLs. Two of the most prominent are described below.

1. Russell Portenoy

127. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and

Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Endo, Janssen, and Purdue (among others), and was a paid consultant to Purdue.

128. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS")/American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

129. Dr. Portenoy also made frequent media appearances promoting opioids. He appeared on *Good Morning America* in 2010 to discuss using opioids long-term to treat chronic pain. On this widely watched program, broadcast in Texas and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[100]

130. Dr. Portenoy put doctors' fear that opioids were dangerous and addictive, and meant only for cancer patients, to rest by arguing that they could be taken safely for months, even years, by patients with chronic pain. Dr. Portenoy, as well as other doctors making the speaker rounds, asserted that "[l]ess than 1% of opioid users became addicted, the drugs were easy to discontinue and overdoses were extremely rare in pain patients." This is wildly incorrect.

131. Perhaps realizing that "[m]ore than 16,000 people die from opioid overdoses every

[100] Good Morning America television broadcast, ABC News, Aug. 30, 2010.

year," Dr. Portenoy is now having "second thoughts" about the "wider prescription" of drugs like Vicodin, OxyContin, and Percocet. Dr. Portenoy later admitted in a 2010 videotaped interview that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks.

132. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist." Dr. Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well…I guess I did."

133. Before his moment of clarity, Dr. Portenoy co-authored a guide to publicize the benefits of opioids for chronic pain, which was paid for by an unrestricted education grant from Endo, titled *A Clinical Guide to Opioid Analgesia* ("*Opioid Analgesia*").[101] *Opioid Analgesia* reiterated that opioids are "absolutely necessary" for pain relief.[102]

134. Although *Opioid Analgesia* claimed "to help clinicians make practical sense of the varied and often conflicting pharmacologic, clinical and regulatory issues to promote the most healthful outcomes possible for patients in pain,"[103] the reality was that it expressed regret that federal and state governments had passed controlled substances acts to stem addiction, which had curtailed the prescription of opioids.[104] This regulation, explained *Opioid Analgesia*, "contributed to the underuse of opioid medications."[105]

135. As with all other books, guidelines, and CMEs promoted by Front Groups and KOLs, *Opioid Analgesia* peddled the alleged absolute need for opioids in light of the chronic pain

[101] Perry G. Fine, M.D. and Russell K. Portenoy, M.D., *A Clinical Guide to Opioid Analgesia*, McGraw-Hill, 2004.
[102] *Id.* at 2.
[103] *Id.* at 3.
[104] Fine, *supra.*
[105] *Id.* at 6.

epidemic. "Because pain is inherently subjective, patient self-report is the 'gold standard' for assessment."[106] If there is no discernible reason for the pain, then it should be characterized as "idiopathic."[107] Regardless of how the pain is characterized, the solution, per *Opioid Analgesia,* is opioids.

136. "While opioid analgesics are controlled substances, they are also essential medication and are absolutely necessary for relief of pain."[108] "Opioid analgesics should be accessible to all patients who need them for relief of pain."[109] Brushing away any concerns about addiction, *Opioid Analgesia* posits that "[a] patient who has reached middle age without developing compulsive use behaviors to potentially abusable drugs, including alcohol and nicotine, appears to be at a very low risk" of addiction, especially if "there is no family history of addiction."[110]

137. Underplaying the risks of addiction, *Opioid Analgesia* falsely claimed that "[o]verall, the literature provides evidence that the outcomes of the drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications."[111] Even while admitting there is "very little information about the risks of misuse, abuse, or addiction among different opioid-treated populations" and even admitting that "[w]hen misused, opioids pose a threat to society,"[112] Defendants' intentionally marketed opioids as effective and safe for treatment of chronic pain and summed up the risk of addiction for short-term therapy as "rare."[113]

[106] Fine, *supra,* at 34.
[107] *Id.* at 35.
[108] *Id.* at Table 1.
[109] *Id.*
[110] *Id.* at 21.
[111] *Id.*
[112] *Id.* at 31, 2.
[113] Fine, *supra*, at 34.

138. Of course, when addiction is as narrowly defined as it is in the books, CMEs, and guidelines that Defendants publish, the risk of addiction would be termed as "rare." The behaviors cited in *Opioid Analgesia* as "probably more suggestive" of addiction included:

- Selling prescription drugs;
- Forging prescriptions;
- Stealing or "borrowing" drugs from others;
- Injecting or inhaling (snorting, smoking) oral formulations; and
- Obtaining the prescription drugs from nonmedical sources.[114]

139. Whereas the following behaviors are "probably less suggestive" of addiction:

- Aggressive complaining about the need for more drug;
- Drug hoarding during periods of reduced symptoms;
- Requesting specific drugs; and
- Using the drug, without approval, to treat another symptom.[115]

140. Instead of these behaviors being symptoms of possible addiction, Dr. Portenoy terms these behaviors as a "phenomenon" termed "pseudoaddiction."[116] Pseudoaddiction allows physicians to discount these behaviors because "they are driven by desperation surrounding unrelieved pain" and are "eliminated by measures that relieve the pain, such as an increase in medication."[117] Instead of treating the "less suggestive" symptoms for what they are – signs of addiction.

141. *Opioid Analgesic* was a success for Defendants in that it has been and continues to be used extensively in CMEs, pamphlets, and reading lists for physicians looking for information

[114] *Id.* at 85.
[115] *Id.*
[116] *Id. at 35.*
[117] *Id.*

regarding opioids. For example, *Opioid Analgesia* was recently cited in a presentation at the University of North Texas College of Pharmacy on April 28, 2017, entitled *Adverse Drug Events Associated with Opiate-Based Pain Management*. It has also been listed as a reference for a CME entitled *The Management of Opioid-Induced Constipation* published by the University of North Texas Health Science Center, which was valid for CME from May 2009 to May 2010. Finally, the book was included in the suggested reading list for a seminar entitled *When Opioids Are Indicated for Chronic Pain* presented on March 26, 2011, in Houston, Texas.

2. Lynn Webster

142. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise-unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports using opioids for chronic pain. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements recommending Opana ER. Dr. Webster authored numerous CMEs sponsored by Endo and Purdue while he was receiving significant funding from Defendants.

143. In 2011, Dr. Webster presented a program via webinar sponsored by Purdue titled *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended using risk screening tools, such as urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths," which was available to and was intended to reach doctors treating Rockwall County residents.

144. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's

dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases…should be the clinician's first response." Endo distributed this book to doctors.

145. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[118] Dr. Webster also admits that "[i]t's obviously crazy to think that only 1% of the population is at risk for opioid addiction."[119]

c. Front Groups Surreptitiously Bankrolled by Defendants Affirmed Defendants' Falsities.

146. Defendants entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for treating chronic pain. Under Defendants' direction and control, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored using opioids for chronic non-cancer pain. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit prescribing opioids in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

147. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure these Front Groups would generate only the messages Defendants wanted to distribute. Even so, the Front Groups held themselves out as independent and as serving

[118] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL, Feb. 19, 2012.
[119] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec.17, 2012.

the needs of their members – whether patients suffering from pain or doctors treating those patients.

148. Defendants Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

1. American Pain Foundation ("APF")

149. APF was founded in 1997 and professed to be an independent non-profit 501(c)(3) organization "serving people with pain through information, advocacy and support."[120] It had a membership of "close to 100,000 and growing" in 2010 and claimed to be the "largest advocacy group for people with pain."[121] The APF lauded its participation in "close to 100 policy activities," which included testifying at legislative hearings to securing state and local proclamations for Pain Awareness Month.[122]

150. APF, however, as the most prominent of Manufacturing Defendants' Front Groups, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next at $1.7 million. Despite the influx of funds from pharmaceutical companies, APF claimed to be an independent patient advocacy group.

151. In 2009 and 2010, more than 80% of APF's operating budget came from

[120] American Pain Foundation, *Treatment Options: A Guide for People Living with Pain*, www.painfoundation.org; *see also 2010 Annual Report*, American Pain Foundation.
[121] *2010 Annual Report*, *supra*.
[122] *Id.*

pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009. In 2010, Endo paid APF more than $1 million and Purdue paid APF between $1 million and 4.9 million.[123] By 2011, APF was entirely dependent on incoming grants from Purdue, Endo, and others to avoid using its line of credit. One of its board members, Russell Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

152. APF issued education guides for patients, reporters, and policymakers that recommended opioids for chronic pain while trivializing their risks, particularly the risk of addiction. Its *Pain Community News*, an "esteemed" quarterly newsletter, had a print circulation of more than 68,000 plus additional online readers.[124] Its monthly electronic newsletter, *Pain Monitor*, was a monthly newsletter that provided links to pain-related news and research.[125] The APF also provided "patient representatives" for Defendants' promotional activities, including Purdue's *Partners Against Pain*[126] and Janssen's *Let's Talk Pain.*[127]

153. In one of its publications, *Treatment Options: A Guide for People Living with Pain*, ("*Treatment Options*"), APF recognized contributions from Cephalon and Purdue.[128] *Treatment Options* was reviewed by Scott Fishman, M.D., Vice Chairman of the APF Board of Directors, and Russell Portenoy, M.D., a Member of the APF Board of Directors and also a KOL.[129] *Treatment Options* set the stage for prescribing opioids by explaining their underuse despite their

[123] *2010 Annual Report, supra*.
[124] *Id.* at 2.
[125] *2010 Annual Report, supra*, at 2.
[126] In its "Partner against Pain" website, Purdue claimed that the risk of addiction from the use of OxyContin in treating "chronic non-cancer pain" was "extremely small"; *see also* Zee, Ex. B, at 3.
[127] *Let's Talk Pain* was a "coalition effort that focus[ed] on supporting positive patient-provided communications" regarding pain.
[128] *Treatment Options, supra,* at ii.
[129] *Id.* at iv.

benefits.[130] It dismissed the risk of addiction with the rhetoric that physical dependence was nothing more than symptoms or signs of withdrawal that occurred when opioids were stopped suddenly or the dose lowered too quickly.[131]

154. *Responsible Opioid Prescribing* and *The War on Pain* both had a tremendous impact on doctors' prescribing habits. In 2000, Scott Fishman, M.D., who served on APF's board, co-authored *The War on Pain* ("*Pain War*") as general authoritative information about pain medicine."[132]

155. *Pain War* seeks new specialties in which opioids can be prescribed for chronic pain. Rheumatologists treating arthritis have been overlooked because they were more prone to prescribe NSAIDS instead of opioids, such as morphine.[133] But such "outdated ideas about addiction and concerns about social stigmas" need to evolve because opioids offer "substantial relief" with "less severe long-term side effects than chronic anti-inflammatories."[134]

156. *Pain War* advocates for physical dependence to opioids, and equates withdrawal symptoms from opioid drugs to that of cessation of coffee drinking. A "pain patient who is dependent on opioids finds life restored," the book advises, and then explains that removing a patient from opioids causes physical, not psychological, consequences, like quitting *coffee*.[135] Addiction to opioids is treated as a "phobia" or "notion" that "using opioids" are "always addictive."[136]

157. *Pain War* censures the failure to prescribe opioids and even suggests that such

[130] *Treatment Options, supra* at 11.
[131] *Id.* at 14 (referring to symptoms such as sweating, rapid heart rate, nausea, diarrhea, goosebumps, and anxiety).
[132] Scott Fishman, M.D., with Lisa Berger, *The War on Pain,* First Quill, 1st ed., 2000.
[133] *Id.* at 154.
[134] Fishman, *War on Pain*, *supra,* at *155.*
[135] *Id.* at 187.
[136] *Id.* at 185.

failure is a criticism of the patient. For example:

> Doses tend to be too low, the right narcotic preparation tends to be avoided, and the prescribing period is often too short. Medicine's reluctance to use appropriate doses of opioid drugs gives patients the wrong message – their pain isn't that important, they are not trustworthy, they may be addicts, they are bad people if they take drugs even if they are prescribed.[137]

158. *Pain War* was distributed across the nation, and sold in Texas, as evidence by a seller from Texas offering the used book for $15.99 plus $5.99 in shipping costs on Amazon.com.

159. As late as 2008, the APF was still relaying the same message. In *A Reporter's Guide: Covering Pain and Its Management* ("*Reporter's Guide*"), the APF extolled that "[t]he person with pain is the authority on the existence and severity of his/her pain. The self-report is [the] most reliable indicator." The *Reporter's Guide* referred to pain as a health crisis and concluded that it affected more Americans than "diabetes, heart disease and cancer combined."

160. Yet APF, Defendants' Front Group also knew that:

- 71% of people abusing prescription pain relievers received them from a friend or family member without a prescription;
- Approximately 2.2 million Americans abused pain medication for the first time in 2006; and
- Between 1992 and 2002, reported abuse by teenagers increased by 542%.

161. Even though Defendants knew about the risks involved in prescribing opioids or ingesting opioids, they continued to disseminate a story about a "pain epidemic" that could be treated only through the use of opioids. Even a 542% increase in abuse by teenagers in the United States in the span of ten years did not make Defendants change their marketing strategy or otherwise modify their educational or promotional materials concerning the risks associated with the use of opioids.

[137] Fishman, *War on Pain*, *supra.*

162. In addition to these publications, APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their "right" to pain treatment, namely opioids. APF's local and national media efforts resulted in 1,600 media stories on pain in 2010, which was an increase of 1,255% from 2009. APF surmised that it reached more than 600 million people with information and education related to pain. All of the programs and materials were available nationally and were intended to reach patients and consumers in Rockwall County.

163. APF's website was visited by nearly 275,000 people in 2010 and a National Pain Foundation was expected to be complete in 2011. In May 2012, the U.S. Senate Finance Committee began investigating the financial ties between Front Groups and trade organizations, such as APF and the FSMB, and the opioid manufacturers. This investigation not only caused damage to APF's credibility but caused Defendants to cease its funding.

164. The Senate Finance Committee intended to investigate whether pharmaceutical companies were responsible for the opioid epidemic by "promoting misleading information about the drugs' safety and effectiveness."[138] The Senate Finance Committee was concerned that a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers…helped create a body of dubious information 'favoring opioids' that can be found in prescribing guidelines, patient literature, position statements, books and doctor education courses."[139]

165. The Senate Finance Committee was especially concerned that "[a]mong the FSMB's educational initiatives has been the development and distribution of a guidebook intended

[138] *See* Letter to Dr. Humayun J. Chaudhy dated May 8, 2012 from Charles E. Grassley and Max Baucus, at p. 2.
[139] *Id. quoting* Milwaukee Journal Sentinel/MedPage Today, *Follow the Money: Pain, Policy, and Profit*, Feb. 19, 2012, *available at* http://medpagetoday.com/Neurology/PainManagement/31256.

to help physicians recognize the risk of opioids and follow responsible and safe prescribing standards."[140] Hence, Dr. Fishman and his book *Opioid Prescribing: A Physician's Guide*, the first edition of which was released in 2007 and later accredited by the University of Wisconsin School of Medicine and Public Health, was at the center of the investigation.[141]

166. The Senate Finance Committee asked for any grants or financial transfers used to produce the book, the revenue generated from the sale of the book, each state that distributed the book, and the names of any people or organization involved in writing or editing the book.[142]

167. Within days, APF's board voted to dissolve the organization and it ceased to exist. The FSMB responded to the Senate Finance Committee's inquiry, however, and agreed that "the abuse and misuse of opioids is a serious national problem."[143] Dr. Chaudhy, speaking on behalf of the FSMB, acknowledged that "prescription drug abuse and related deaths has grown at an alarming pace in the United States."[144] Dr. Chaudhy described Dr. Fishman, the author of *Opioid Prescribing*, as "one of the nation's leading experts in pain medicine."[145]

168. *Opioid Prescribing* was released from 2007 through January 2012, was distributed in each of the 50 states, including Texas, and supported in the medical community as an educational resource for doctors.[146] The book is still being sold today on websites such as Amazon and Ebay. Dr. Fishman also toured and gave keynote speeches about *Opioid Prescribing*. For example, Dr. Fishman presented the keynote at the Federation of State Medical Board Meeting in

[140] Chaudhy Letter, *supra*, at 5 (emphasis in original).
[141] *Id.*
[142] *Id.* at 3.
[143] Letter to Max Baucus and Charles Grassley dated June 8, 2012 from Humayun J. Chaudhy, DO, FACP, at 1.
[144] Chaudhy Letter, *supra*, at 1.
[145] *Id.* at 5.
[146] Chaudhy Letter, *supra.*

Fort Worth, Texas on April 28, 2012, which lasted three days.[147] The book was also used extensively by state regulators to make safe and responsible decisions about prescribing opioids.[148]

169. As described herein, Dr. Fishman and his book were partly funded by Endo and Purdue, among others as evidenced in the response. In 2004, Purdue paid $87,895 in the form of a grant to the FSMB to update the FSMB *Model Guidelines for the Use of Controlled Substances in the Treatment of Pain*, along with other objectives related to opioids.[149] In 2005, Purdue paid $244,000 to FSMB and in 2006, Purdue paid $207,000 to FSMB for the continuation of the same project.[150] In 2008, Endo and Purdue each paid $100,000 in the form of a grant for the distribution of *Responsible Opioid Prescribing*.[151] Thus, from 2000-2012, Purdue paid $734,505.06 and Endo paid $411,620.00 to the FSMB and FSMB Foundation.

170. Dr. Chaudhy's response merely underscored Defendants' role, through KOLs and Front Groups, in controlling the message these groups conveyed about opioids.

2. American Academy of Pain Medicine ("AAPM")

171. The American Academy of Pain Medicine, with Defendants' assistance, prompting, involvement, and funding, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

172. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its

[147] U.C. Davis, *Fishman Gives Keynote at Federation of State Medical Boards Meeting*, May 1, 2012, *available at* https://ucdmc.ucdavis.edu/publish/news/newsroom/6523.
[148] Chaudhy, *supra*, at 5, 17.
[149] *Id.* at 11.
[150] *Id.* at 11-12.
[151] *Id.* at 12.

annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

173. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are…small and can be managed."[152]

174. Defendants influenced AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization. AAPM's staff understood they and their industry funders were engaged in a common task – propagate a "pain epidemic" and solve it by teaching that opioids were safe and effective for treating chronic pain.

175. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed there was a low risk that patients would become addicted to opioids. The

[152] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), *available at* http://www.medscape.org/viewarticle/500829.

co-author of the statement, Dr. Haddox, was a paid speaker for Purdue at the time. Dr. Portenoy, Defendants' KOL, was the sole consultant. The consensus statement remained on AAPM's website until 2011.

176. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend using opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Endo, and Purdue.

177. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because he was concerned the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The Guidelines have been cited 732 times in academic literature, were disseminated in and around Rockwall County during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

B. Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

178. To convince doctors and patients in Rockwall County that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is non-addictive, safe, and effective. Knowing they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Manufacturing Defendants made

claims that were not supported by, and were contrary to, the scientific evidence. Defendants have not corrected their misrepresentations.

179. Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risks of addiction and overdose, through a series of misrepresentations that have since been conclusively debunked by numerous published studies and the magnitude of human misery caused by Defendants' deceptions. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that opioids are the best treatment option for any recurrent moderate pain because: (1) only a miniscule number of patients, if any, would become addicted; (2) all patients with a substantial risk of becoming addicted to opioids could be readily identified; (3) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (4) the use of higher opioid doses do not escalate risk of addiction or overdose; and (5) "abuse-deterrent" opioids are reliably safe and effective for perpetual use. Defendants still espouse these misrepresentations today.

180. ***First***, Defendants falsely claimed the risk of addiction is low and unlikely to develop when opioids are prescribed, as opposed to those obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. For example:

a) Actavis's predecessor caused a patient education brochure to be distributed in 2007 claiming opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond;

b) Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online;

c) Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.";

d) Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com;

e) Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.";

f) Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated";

g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online; and

h) Detailers for Purdue, Endo, and Janssen in and around Rockwall County minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for opioid abuse with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

181. These claims contradict empirical evidence. As noted by the CDC, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])."[153] The CDC has explained that "[o]pioid pain medication use presents serious risks, including…opioid use disorder" and that "continuing opioid therapy for

[153] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, 65:1 Morbidity and Mortality Weekly Report 1, 15 (Mar. 18, 2016).

3 months substantially increases risk for opioid use disorder."[154] Among the 12 recommendations by the new CDC guidelines to improve patient care and safety is that non-opioid therapy is preferred for chronic pain unless there is active cancer or it is for palliative and end-of-life care.[155]

182. Defendants' long-standing claims that opioid addiction and overdose are anomalies largely attributable to patient abuse of the drug, are demonstrably false. Indeed, the majority of cases involving injury and death occur in people using opioids ***exactly*** as prescribed .

183. In 2010, a study addressed the rates of opioid overdose with patients receiving average prescribed daily opioids versus patients receiving medically prescribed chronic opioid therapy.[156] The patients included those receiving three-plus opioid prescriptions within 90-days for chronic non-cancer pain between 1997 and 2005.[157] Patients who received 50-99 mg had a 3.7-fold increase in overdose risk (95% C.I. 1.5, 9.5) and a 0.7 annual overdose rate.[158]

184. The authors determined that even though opioids provide some pain relief for chronic pain, balancing the long-term risks with the benefits was still "poorly understood."[159] Those patients who had not received opioids lately had a lower risk of overdose, however, than patients consistently receiving opioids at a low dosage.[160]

185. The authors pointed to previous studies that indicated a rise in opioid-related overdoses with an increase in prescribing opioids for non-cancer pain, but the belief that such phenomenon was caused by patients obtaining opioids from non-medical sources.[161] This study,

[154] *Id.* at 2, 25.
[155] *Id.* at 16.
[156] Kate M. Dunn, Ph.D., Kathleen W. Saunders, J.D., *Overdose and Prescribed Opioids: Association among Chronic Non-Cancer Pain Patients*, Ann. Intern. Med. (Dec. 10, 2010), at 2.
[157] *Id.*
[158] *Id.*
[159] *Id.*
[160] Dunn, *supra,* at 6.
[161] *Id.* at 7.

however, proves for the first time that the risk of overdose is directly linked to the prescription and use of medically prescribed opioids.[162]

186. The authors of a Washington study in which the authors obtained Washington Medicaid data from the Washington Heath Care Authority reached a similar conclusion.[163] The opioid prescription claim history was examined for each "opioid poisoning" for the months that enrollees received Medicaid FFS prescription benefits.[164] The authors concluded that a large percentage of opioid poisonings happened at lower prescribed doses and in individuals who were not considered chronic users.[165]

187. The authors noted that previous opioid guidelines focused on opioid doses above 80-120 mg/d MED even though previous studies showed risk of opioid deaths and poisonings at much lower doses and that most non-methadone opioid poisonings had been prescribed below these guidelines levels.[166] The authors concluded that only a small percentage of patients are prescribed opioids at a dosage greater than 120 mg/d MED, but that a large percentage of the opioids poisonings have been occurring in patients taking lower doses and in patients not considered chronic users.[167] Overdoses were therefore occurring in patients prescribed opioids for chronic non-cancer pain at increased rates and the overdose risk increased with an average prescription dose.[168] The guidelines and other educational material regarding opioids need to be changed to reflect the opioid poisoning among this population.[169]

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[162] *Id.*
[163] Deborah Fulton-Kehoe, Ph.D., *Opioid Poisonings in Washington State Medicaid: Trends, Dosing, and Guidelines*, 53 Medical Care 8 (Aug. 2015), at 680.
[164] *Id.*
[165] *Id.*
[166] Fulton-Kehoe, *supra* at 683.
[167] *Id.* at 684.
[168] Fulton-Kehoe, *supra.*
[169] *Id.*

188. In fact, "[t]he majority of deaths (60%) occur in patients when they are given prescriptions based on prescribing guidelines by medical boards with 20% of deaths in low dose opioid therapy…." The way to cure the "crisis of opioid use in the United States" is to change "inappropriate prescribing patterns, which are largely based on a lack of knowledge, perceived safety, and inaccurate belief of undertreatment of pain."

189. Another study found that approximately 60% of overdoses occur in medical users of opioids prescribed by a single physician to manage chronic pain. Non-medical users comprise only a statistical minority of opioid overdoses.

190. Scientific evidence underscores the conclusion that low-dose opioid therapy for chronic pain, opioids taken as prescribed, opioids obtained from a single doctor, and opioids prescribed pursuant to prescribing guidelines cause many overdoses. Manufacturing Defendants, however, disseminated contrary messaging throughout their marketing campaigns to sell more opioids.

191. ***Second***, Defendants falsely instructed doctors and patients that signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, and Purdue – and claimed that pseudoaddiction is substantiated by scientific evidence. For example:

a) Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition continues to teach that pseudoaddiction is real;

b) Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction…refers to patient behaviors that may occur when pain is under-treated….Pseudoaddiction is different

from true addiction because such behaviors can be resolved with effective pain management.";

c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials;

d) Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."; and

e) Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long- acting opioid.

192. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The CDC Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment…are unlikely to experience pain relief with longer-term use,"[170] and that physicians should "reassess [] pain and function within 1 month"[171] in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids"[172] because the patient is "not receiving a clear benefit."[173]

[170] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.* at 13.
[171] *Id.*
[172] *Id.* at 25.
[173] *Id.*

193. ***Third,*** Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allowed them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting opioid therapy for chronic pain. For example:

a) Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts;

b) Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths;" and

c) As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

194. Once again, the 2016 CDC Guideline confirms these representations are false. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts – widely believed by doctors to detect and deter outcomes related to addiction and overdose.[174] As a result, the Guideline recognizes that doctors should not overestimate the risk screening tools for classifying patients as

[174] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra,* at 14.

high or low risk for opioid addiction because they are insufficient to rule out the risks of long-term opioid therapy.[175]

195. ***Fourth***, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem thereby failing to disclose the increased difficulty of stopping opioids after long-term use.

196. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation."

197. Defendants deceptively minimized the significant symptoms of opioid withdrawal, which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

198. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be limited to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,"[176] because "***physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.***"[177]

[175] *Id.*
[176] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra,* at 24.
[177] *Id.* (emphasis added).

The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence"[178] and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal"[179] and pausing and restarting tapers depending on the patient's response.

199. Contrary to the *Treatment Options* distributed by the APF, withdrawal from opioids involves much more than mere "physical" dependence occurring only when opioids are stopped suddenly, or the dose lowered too quickly.

200. ***Fifth***, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example:

a) Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond;

b) Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online;

c) Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose

[178] *Id.* at 23.
[179] *Id.* at 26.

of medication for your pain.";

d) Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased….You won't 'run out' of pain relief.";

e) Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages;

f) Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will;

g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online;

h) Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages; and

i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.

201. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established"[180] while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[181]

[180] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra,* at 22.
[181] *Id.* at 22-23.

202. More specifically, the CDC explains, "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[182] Similarly, there is an "increased risk for opioid use disorder, respiratory depression, and death at higher dosages."[183] That is why the CDC advises doctors to avoid increasing dosages above 90 morphine milligram equivalents per day.

203. ***Finally***, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids reliably curb addiction and abuse.

204. More specifically, Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter use. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant in a way that suggested it was more difficult to misuse the product. This claim was false.

205. The FDA warned in a 2013 letter that there was no evidence Endo's design would provide a reduction in oral, intranasal or intravenous use.[184] Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

206. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was designed to be or is crush-resistant. The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER.

207. Similarly, the 2016 CDC Guideline states that no studies support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,"[185]

[182] *Id.* at 23-24.
[183] *Id.* at 21.
[184] *See FDA Statement: Original Opana ER Relisting Determination*, May 10, 2013.
[185] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.* at 22.

noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."[186]

208. These numerous, long-standing misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to underestimate those risks.

C. Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy.

209. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants had to persuade them that there was a significant benefit to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine long-term benefits of opioid therapy for chronic pain."[187]

210. In fact, the CDC found no evidence showing "a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[188] and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

211. Nonetheless, Manufacturing Defendants were legion in their misrepresentations that opioid drugs were appropriate for use as a long-term lifestyle. For example:

a) Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives;

b) Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects;

c) Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact"

[186] *Id.*
[187] *Id.* at 19.
[188] *Id.* at 15.

that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs;

d) Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function;

e) *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online;

f) Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012;

g) Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website promoted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site;

h) Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast;

i) Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube;

j) Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today; and

k) Purdue's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

212. These claims are unsupported by the scientific literature. The 2016 CDC Guideline explained, "There is ***no good evidence*** that opioids improve pain or function with long-term use"[189] and "complete relief of pain is unlikely."[190] The CDC reinforced this conclusion throughout its 2016 Guideline:

a) "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later….";[191]

b) "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.";[192] and

c) "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[193]

213. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[194]

214. Defendants also falsely emphasized or exaggerated the risks of competing products like NSAIDs so that doctors and patients would look to opioids first for treating chronic pain. Once again, Defendants' misrepresentations contradicted non-industry sponsored scientific evidence. In addition, Purdue misleadingly promoted OxyContin as unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for

[189] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra,* at 20 (emphasis added).
[190] *Id.*
[191] *Id.* at 15.
[192] *Id.* at 18.
[193] *Id.* at 18-19.
[194] *Id.* at 20.

12 hours – a fact that Purdue has known at all times relevant to this action.

215. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. The reason is that OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. Although the patient experiences a powerful initial response, there is little or no pain relief at the end of the dosing period because less medicine is released.

216. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a substantial number of chronic pain patients taking OxyContin experience it.

217. This "end of dose" failure not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

218. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell doctors in and around Rockwall County that OxyContin lasts a full 12 hours.

D. Defendants also engaged in Other Unlawful, Unfair, and Fraudulent Misconduct.

219. Defendants herein participated in illicit and unlawful prescribing of its drugs. For example, Purdue did not report illegal prescribing of OxyContin until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets. In doing so, Purdue protected its own profits at the expense of public health and safety.

220. The State of New York also found that Endo failed to require sales representatives to report signs of addiction, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

E. Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

221. As part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S. and in and around Rockwall County. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe opioids, but were less likely to be educated about treating pain and the risks and benefits of opioids.

222. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them.

223. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are special risks of long-term opioid use for elderly patients and recommends that doctors use "additional caution" to minimize the risks of opioid use in elderly patients.[195]

224. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

[195] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra,* at 23.

225. Manufacturing Defendants achieved their goal in targeting these vulnerable populations when the Arthritis Foundation published its *Guide to Pain Management* in 2003 ("*Pain Management Guide*").[196] The *Pain Management Guide* was published by a neutral third party that not only believed the message Defendants had been selling for years, but it continued to relay that message to patients experiencing chronic pain – elderly patients with arthritis.[197]

226. The *Pain Management Guide* was intended for a population of "70 million Americans who have arthritis or other related diseases."[198] It parroted falsities, such as the low risk of developing an addiction to opioids and cited Defendants' false statistic: "The addiction rate from narcotics is approximately one percent."[199]

227. The Arthritis Foundation even accepted and repeated Defendants' distinction between dependence and addiction. A person with dependence suggests he or she would experience withdrawal symptoms upon stopping opioids while addiction "is a self-destructive, habitual use" of opioids.[200] The *Pain Management Guide* brushes aside concerns about addiction and recommends higher doses of opioids for patients who develop a dependence on opioids[201] – the exact message that Defendants had been spouting for years.

228. The fact that neutral third parties were relying on and buying Defendants' false propositions only verifies Defendants' successful fraud on the medical and non-medical community at large.

F. Although Defendants knew that their Marketing of Opioids was False and Deceptive, they Fraudulently Concealed their Misconduct.

[196] Susan Bernstein, *The Arthritis Foundation's Guide to Pain Management*, Arthritis Foundation, 2003.
[197] *Id.*
[198] *Id.*
[199] *Id.* at 70-71.
[200] *Id.* at 70.
[201] *Id.*

229. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew their misrepresentations were false and deceptive. Manufacturing Defendants and Distributor Defendants alike knew that the marketing scheme being promoted by the Manufacturing Defendants was misleading, inaccurate, and simply false. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes.

230. In The Journal of the American Medical Association November 2002 edition, which Defendants meant to reach physicians throughout the nation, Purdue advertised OxyContin as a safe drug with minimal safety risks.[202] The ad depicts a man and boy fishing with a title in large white letters exclaiming that "THERE CAN BE LIFE WITH RELIEF" with "LIFE WITH RELIEF" as the largest words in the advertisement.[203] Purdue then informs physicians that "[t]he most serious risk associated with opioids, including OxyContin, is respiratory depression."[204]

231. Purdue fraudulently represented that respiratory depression was not only the most serious risk for its own drug OxyContin, but for opioids in general, even though it knew that opioids carried a risk of addiction and death.

232. The ad continues with benign side effects that may occur with the use of OxyContin, such as "constipation, nausea, sedation, dizziness, vomiting, pruritus, headache, dry mouth, sweating, and weakness."[205] These side effects are certainly a far cry from addiction or death. This ad also claims that OxyContin is a "continuous around-the-clock analgesic," which is

[202] The Journal of American Medical Association, Nov. 13, 2002.
[203] *Id.* at 1, 3.
[204] *Id.*
[205] JAMA, *supra.*

equally false.[206]

233. Because of the bold misrepresentations and omissions in its ads occurring in the October 2, 2002 JAMA issue, and one occurring in the November 13, 2002 issue, the FDA wrote a warning letter to Michael Friedman, the Executive Vice President and Chief Operating Officer of Purdue.[207] Mr. Abrams explained that "[y]our journal advertisements omit and minimize the serious safety risks associated with OxyContin, and promote it for uses beyond which have been proven safe and effective."[208] Mr. Abrams reprimanded Purdue for failing to present "any information" in the advertisement about the "potentially fatal risks" or the potential for abuse associated with OxyContin.[209]

234. Mr. Abrams was concerned that these advertisements suggested such a "broad use of [OxyContin] to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks associated with its use…"[210] Purdue's actions were "especially egregious and alarming" given "its potential impact on the public health."[211] Mr. Abrams pointed out to Purdue the reality that "[i]t is particularly disturbing that your November Ad would tout 'Life with Relief,' yet fail to warn that patients can die from taking OxyContin."[212]

235. Three current and former executives from Purdue plead guilty in 2007 to criminal charges that they misled regulators, doctors, and patients about OxyContin's risk of addiction. In pleading guilty to misbranding charges, Purdue admitted it had fraudulently marketed OxyContin as a drug less prone to addiction and as having fewer side effects than other opioids. In reality,

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[206] JAMA, *supra*, at 1, 3.
[207] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Michael Friedman, Exec. Vice Pres. and COO, Purdue Pharma L.P.
[208] *Id.* at 1.
[209] *Id.*
[210] *Id.* at 2.
[211] *Id.*
[212] *Id.* at 4.

unlike most other opioids, OxyContin contained pure oxycodone without any other ingredients, which made it a higher-dose narcotic despite its time-release design that Purdue hawked as ameliorating its addictive potential.

236. Defendants misrepresented their compliance with their legal duties. Purdue serves as an example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its "strong record of coordination with law enforcement."[213]

237. Manufacturing Defendants avoided detection of their fraudulent conduct by disguising their role in the deceptive marketing through funding and using third parties, such as Front Groups and KOLs. Doctors and patients trusted these third parties and did not realize that it was the pharmaceutical companies that were actually feeding them false and misleading information.

238. Defendants also manipulated their promotional materials and the scientific literature to make it appear that the information promoted was accurate, truthful, and supported by objective evidence when it was not.

239. Thus, Defendants successfully concealed from the medical community and patients facts sufficient to arouse suspicion of the claims Rockwall County now asserts. Rockwall County did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

G. By Increasing Opioid Prescriptions and Use, Defendants' Deceptive Marketing

[213] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label* (May 5, 2016), https://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, (July 11, 2016), https://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

Scheme has fueled the Opioid Epidemic and Damaged Rockwall County Communities.

240. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies reveal that many doctors and patients are unaware of or do not understand the risks or benefits of opioids. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[214]

241. Defendants' deceptive marketing scheme caused, and continues to cause, doctors in and around Rockwall County to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' fraud, these doctors would not have prescribed as many opioids that negatively impacted residents of Rockwall County.

242. Defendants' deceptive marketing scheme allowed Individual Defendants to promote, over-prescribe, and financially benefit from prescribing opioids for to patients complaining of chronic pain.

243. Dr. Richard Andrews was a co-owner and supervising physician of McAllen Medical Clinic in Dallas, Texas.[69] Dr. Andrews was indicted on December 1, 2015 for, among other things, conspiracy to distribute a controlled substance.[70] On July 26, 2016, Dr. Andrews entered into a plea agreement in which he pleaded guilty.[71] On March 3, 2017, Dr. Andrews and the Texas Medical Board agreed that his license would be revoked in lieu of further disciplinary actions.

[214] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities*, Jan. 27, 2016, *available at* http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction.

244. Dr. Theodore Okechuku operated a pain clinic in Lake Highlands located in Dallas, Texas.[73] Dr. Okechuku was indicted on December 3, 2013 for conspiracy to unlawfully distribute a controlled substance. Dr. Okechuku violated the terms of his pre-trial release because he continued to prescribe hydrocodone and other controlled substances. Ultimately, Dr. Okechuku was found guilty on 3 counts, one related to the distribution of opioids, and sentenced to 25 years.

245. Dr. Nicolas A. Padron operated a "cash only" clinic in Dallas. He, too, was indicted for conspiracy to unlawfully distribute controlled substances and ultimately sentenced to 87 months in federal prison. On May 2, 2014, Dr. Padron agreed to the revocation of his medical license in lieu of further disciplinary action.

246. If the manufacturing and distributing Defendants were not over-supplying opioids, then physicians like Dr. Andrews, Dr. Okechuku, and Dr. Padron could not devise schemes to prescribe opioids without a legitimate purpose as a means to flood the open market with opioids, such as OxyContin, Hydrocodone, and Vicodin. Defendants' deceptive marketing scheme also caused, and continues to cause, patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

247. Defendants' deceptive marketing has caused and continues to cause the prescription and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

248. The escalating number of opioid prescriptions written by doctors who were

deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Rockwall County. The increase in opioid prescriptions equals an increase in "disability, medical costs, subsequent surgery, and continued or late opioid use."

249. Scientific evidence demonstrates a strong correlation between opioid prescriptions and addiction to opioids. In a 2016 report, the CDC explained that prescribing opioids has quadrupled since 1999, which has resulted in a parallel increase in opioid overdoses.[215] Indeed, there has been a two-third increase in overdose deaths from using opioids since 2000.[216] For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic."[217]

250. Due to the increase in opioid overdoses, first responders, such as police officers, have been and will continue to be in the position to assist people experiencing opioid-related overdoses.[218] In 2016, "over 1,200 law enforcement departments nationwide carried naloxone in an effort to prevent opioid-related deaths."[219]

251. Defendants' deceptive marketing scheme has also detrimentally impacted children in Rockwall County. Overprescribing opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household.

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[215] CDC/NCHS, *National Vital Statistics System, Mortality*, CDC Wonder, Atlanta, GA: US Department of Health and Human Services, 2016, *available at* https://wonder.cdc.gov/; Rudd RA, Seth P, David F, Scholl L, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, Morb Mortal Wkly Rep., Dec. 16, 2016.
[216] CDC, *National Vital Statistics System*, *Mortality*, Morb Mortal Wkly Rep., Jan. 1, 2006, at 1378-82, Increases in Drug and Opioid Deaths – United States, 2000-2014.
[217] *CDC Guideline for Prescribing Opioids for Chronic Pain, supra; see also* Rudd, *supra*.
[218] Tex. Att'y Gen. Op. No. KP-0168 (2017).
[219] *Id. citing* http://www.nchrc.org/law-enforcement/us-law-enforcement-who-carry-naloxone/.

252. Defendants' conduct has adversely affected Rockwall County's child protection agencies in the number of children in foster care driven by parental drug addiction. Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more expensive for counties like Rockwall County.

253. Opioid addiction is one of the primary reasons that Rockwall County residents seek treatment for substance dependence. A significant number of admissions for drug addiction were associated with a primary diagnosis of opiate addiction or dependence.

254. But for Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market, this opioid crisis would not have occurred and Rockwall County would not have been harmed. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids to which people are addicted come, directly or indirectly, through doctors' prescriptions.[220]

255. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. For example, heroin use has more than doubled in the past decade among adults aged 18 to 25 years.[221] Moreover, heroin-related overdoses in the United States has more than quadrupled since 2010.[222]

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[220] Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care, Apr. 19 2013, at 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), *available at* http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers.

[221] Centers for Disease Control and Prevention, *Vital Signs: Today's Heroin Epidemic – More People at Risk, Multiple Drugs Abused*, MMWR 2015, *available at* https://www.cdc.gov/vitalsigns/heroin/index.html.

[222] *Id.*

256. The costs and consequences of opioid addiction are staggering. For example, in 2007, the cost of healthcare due to opioid addiction and dependence was estimated at 25 billion, the cost of criminal justice was estimated at 5.1 billion, and the cost of lost workplace productivity was estimated at 25.6 billion.

257. Texas had the second highest healthcare costs in 2015 from opioid abuse in the nation totaling $1.96 billion.[223] One in five Texas high school students has taken prescription drugs without a valid prescription.[224] And four of the top 25 cities for abuse in the United States – two of them located in East Texas – is in Texas.[225] In 2017, the Sulphur Spring News-Telegram announced a "PANDEMIC" of opioid addiction in America that included Rockwall County.[226]

258. The above stated allegations and Defendants' creation of the opioid epidemic are supported by the Texas State Legislature. Recognizing that the epidemic related to opioids and substance abuse is directly affecting many people throughout the United States and Texas, the Honorable Joe Straus, Speaker of the Texas House of Representatives, on October 23, 2017 appointed thirteen members from across the state to the Select Committee on Opioids and Substance Abuse (Committee) for the 2017/2018 interim. On November 12, 2018, the House Select Committee on Opioids and Substance Abuse submitted its interim report,[227] which found the following:

a) The opioid epidemic and substance abuse in Texas is real[228];

b) The current epidemic is fueled by two primary factors, the unsubstantiated

[223] Craig, *Pandemic*, *supra*.
[224] *Id.*
[225] *Id.*
[226] Kerry Craig, *PANDEMIC - Opioid Addiction Results in one Woman's Daily Struggle*, Sulphur Springs News-Telegram, Oct. 7, 2017, *available at* https://www.ssnewstelegram.com/news/opioid-addiction-results-in-one-woman-s-daily-struggle/article_bded4eoa-ab80-11e7-a252-d3f304e26628.html.
[227] https://house.texas.gov/_media/pdf/committees/reports/85interim/Interim-Report-Select-Committee-on-Opioids-Substance-Abuse-2018.pdf
[228] *Id* at p. 90

claims that were made in the 1980s about opioid addiction being rare and the increased prescription rates for opiates seen between the 1990s and the 2010s. Opioids also became easier and cheaper to obtain illegally. In 2000, "Pain as the Fifth Vital Sign" was introduced by the Joint Commission as a standard to measure the performance of healthcare providers. This was reinforced by patient satisfaction surveys and accreditation standards and may have contributed to the increased prescribing of opioids;[229]

c) In 2017, over 30,000 drug exposure calls were made to the Texas Poison Control Center Network, including 5,265 for opioid exposure;[230]

d) About 5 percent of Texas college students reported misusing opioids in 2017;[231]

e) About 54 percent of offenders within the Criminal Justice System are identified as needing some level of substance abuse treatment; of these, 70 percent need invasive treatment;[232]

f) Within the Department of Family Protective Services (DFPS), caregiver substance abuse contributed to 68 percent of removals of children;[233]

g) The opioid crisis costs Texas $20 billion annually;[234]

h) For U.S. hospitals, the cost of treating an opioid overdose victim in intensive care units rose 60 percent between 2009 and 2015;[235]

i) Death certificate data shows that overall, accidental drug overdose deaths in Texas has been rising since 1999, and opioid related deaths contributed to almost half of the total accidental overdose deaths in 2015;[236]

j) Texas' county data shows higher numbers of opioid-related inpatient admissions in the Dallas/Fort Worth (DFW) metroplex, the Houston area, and along the I-35 corridor. Also, the county data shows that accidental opioid-related deaths are more prevalent in East Texas, and the DFW and Houston metro areas[237];

[229] *Id* at p. 9
[230] *Id* at p. 10
[231] *Id* at p. 10
[232] *Id* at p. 11
[233] *Id* at p. 11
[234] *Id* at p. 11
[235] *Id* at p. 11
[236] Interim Report, *supra* at p. 20
[237] *Id* at p. 21

k) One out of sixteen people prescribed opioids will become addicted[238];

l) Seven days, the number of days needed to become dependent on or addicted to prescription opioids[239];

m) Nationally, 80 percent of all heroin users first started with prescription opioids[240];

n) In the U.S., opioid misuse contributes to over 420,000 emergency department visits each year[241];

o) In Texas, an overnight opioid overdose admission costs over $36,000[242];

p) A JAMA study released in March of 2018 reported that treatment with opioids was not superior to treatment with non-opioid medications for improving pain-related function over 12 months. These two recent studies highlight that in many cases a potentially addictive prescription opioid may not be necessary to manage one's pain and that other treatment options are just as viable[243];

q) Neonatal abstinence syndrome (NAS) is a set of symptoms that can occur in a newborn that has been prenatally exposed to opioids while in the mother's womb. Upon birth, exposure to opioids is abruptly stopped, and the baby will experience symptoms of withdrawal such as gastrointestinal problems, crying, feeding issues, and sensitivity to stimuli in the environment. Substance use among pregnant women impacts the health of the mother and child and is affected by access to and availability of services specific to pregnant women[244];

r) Rates of NAS diagnoses in Texas are increasing: Texas Medicaid saw 1,150 diagnoses in 2011 and over 1,300 diagnoses in 2015[245];

s) Texas has a higher NAS average hospital length of stay than national average; the average hospital length of stay for NAS in Texas is 21 days while the average is about two weeks[246]; and

t) From 2012 to 2015, 382 maternal deaths in Texas occurring within

[238] *Id* at p. 34
[239] *Id* at p. 34
[240] *Id* at p. 34
[241] *Id* at p. 34
[242] *Id* at p. 34
[243] *Id* at p. 37
[244] *Id* at p. 37
[245] Interim Report, *supra* at p. 38
[246] *Id* at p. 38

> 365 deaths of pregnancy were confirmed, and opioids were involved in 37 (58 percent) of maternal drug overdose deaths[247].

259. Prescription opioid addiction and overdose have an enormous impact on the health and safety of individuals, as well as communities at large, because the consequences of this epidemic reach far beyond the addicted individual.

260. Rockwall County has also expended funds for false claims submitted on the County's health plans that were paid as medically necessary when they were not and prescriptions for opioids through worker's compensation benefits.

261. The repercussions for residents of Rockwall County therefore include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration, which results in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers, and law enforcement. Manufacturing Defendants knew, and should have known, about the harms that their deceptive marketing has caused, and continues to cause, and will cause in the future. Manufacturing Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding.

262. Manufacturing Defendants also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. Manufacturing Defendants not only knew, but intended that their misrepresentations would persuade doctors to prescribe and encourage patients to use their opioids for chronic pain.

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[247] *Id* at p. 38

263. Manufacturing Defendants' actions are neither permitted nor excused by the fact that their drug labels may have allowed, or did not exclude, the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Manufacturing Defendants' misrepresentations were directly contrary to pronouncements by, and guidance from, the FDA based on the medical evidence and their own labels.

264. Nor is Manufacturing Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed decisions. And both doctors and patients in Rockwall County relied on information Manufacturing Defendants distributed whether it was through ads, magazines, trade journals, websites, CMEs, KOLs, and/or front groups. Manufacturing Defendants also hijacked what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

265. Likewise, Distributor Defendants knew when there was suspicious opioid prescription activity as they do today. They were in a unique position to forestall the epidemic in Rockwall County before it began. Instead, Distributor Defendants allowed a flood of opioids to be poured into Rockwall County. Rockwall County relied on Distributor Defendants to prevent oversupply with distribute prescription drugs, including opioids, only if a valid medical purpose existed. At the very least, Rockwall County depended on Distributor Defendants to act as watchful and effective gatekeepers in the opioid pipeline as they represent in their public statements. Distributor Defendants did neither to Rockwall County's detriment, proximately causing damage to Rockwall County.

266. The funds that Rockwall County has used and will continue to use for all the costs associated with Defendants' false, misleading, and fraudulent marketing are taxpayer funds. Defendants specifically targeted physicians in Rockwall County with fraudulent claims concerning the benefits of opioids for chronic pain while omitting the lack of efficacy.

267. Defendants also fraudulently omitted the fact that opioids were addictive even though they knew, or should have known, that physicians in Rockwall County would either use the misinformation Defendants relayed to them to prescribe opioids to Rockwall County residents or give this information to Rockwall County residents, resulting in the over-prescribing and/or overuse of opioids in Rockwall County.

268. Defendants' actions and omissions were each a cause-in-fact of Rockwall County's past and future damages. Defendants' wrongful conduct caused injuries to Rockwall County in the past, continues to cause injuries to Rockwall County, and will continue to cause injuries to Rockwall County in the future. Future damages include, but are not limited to, additional resources for counseling and medication assisted treatment of addicts, medical treatment for overdoses, life skills training for adolescents, increased law enforcement, and additional resources to treat the psychological effects of opioids and the underlying conditions that make people susceptible to opioid addiction, all of which will be obtained through taxpayer resources.

H. Distributor Defendants Knew that Opioids were being Fraudulently Prescribed and Failed to Act.

269. Distributor Defendants are not innocent sellers of opioid drugs. Distributor Defendants knew that the marketing scheme promoted by Manufacturing Defendants was misleading, false, and deceptive. They knew that opioids were being industry promoted for the treatment of virtually any complaint of recurrent pain, and advertised as less addictive, less prone

to abuse, less threatening for overdose, and more effective for perpetual use than was true. Nevertheless, they have deliberately shirked their duties to monitor suspiciously high prescription patterns, and have continued to feed the over-prescribing of opioid drugs. Distributor Defendants have long been aware of an opioid overuse epidemic in America, in Texas, and in Rockwall County, but chose in each instance to profit by stoking those epidemics with more opioids. Distributor Defendants knew that opioids were too often being prescribed without legitimate therapeutic purpose, but continued to inundate the market with opioids. Distributor Defendants were and continue to be an integral part of the Rockwall County opioid epidemic.

270. As early as 2008, Distributor Defendants knew there was an opioid crisis and they were failing in their "critical role" in the supply chain to change or decrease the number of opioids being distributed into the market. McKesson paid a $13.25 million fine to settle claims regarding suspicious orders of opioids from internet pharmacies in 2008.[248] Cardinal paid a $34 million fine for failing regarding suspicious distribution of hydrocodone in 2008.[249] Cardinal also had to close down its Lakeland, Florida warehouse because it turned a blind eye to the abundance of opioids funneling through only four pharmacies.[250] As such, McKesson and Cardinal knew by 2008, that their opioids were too often being oversupplied and distributed and, upon information and belief, that suspicion for diversionary purposes existed. This knowledge should have caused McKesson and Cardinal to better perform their duties to monitor non-therapeutic opioid prescription orders and to refrain from filling these orders as they occurred in Rockwall County. But instead McKesson and Cardinal doubled-down on profiting from an opioid epidemic, and did so in the Rockwall County opioid epidemic.

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[248] Eric Eyre, *"Suspicious" Drug Order Rules Never Enforced by State*, Charleston Gazette Mail, Dec. 18, 2016, *available at* www.wvgazettemail.com.
[249] *Id.*
[250] *See* Eyre, *supra*.

271. No later than 2011, all Distributor Defendants knew there was a public health crisis throughout America created by opioid use. In 2011, the CDC announced that very thing. And in 2017, the Sulphur Spring News-Telegram announced a "PANDEMIC" of opioid addiction in America that included Rockwall County.[251]

272. Texas law specifically requires that dispensers like Distributor Defendants monitor opioid prescription orders and to refuse to fill prescription orders for opioids that are without valid medical purpose. In spite of the existence of an opioid epidemic in Rockwall County, and the fact that Distributor Defendants knew or should have known of that epidemic, Distributor Defendants continued to fill each opioid prescription order in Rockwall County, including those that were without valid medical purpose--thus stoking the epidemic.[252]

273. The Distributor Defendants publicly but inaccurately portrayed themselves as committed to working to prevent diversion of dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program" to identify and block orders that do not meet a strict criteria. Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as

[251] Kerry Craig, *PANDEMIC - Opioid Addiction Results in one Woman's Daily Struggle*, Sulphur Springs News-Telegram, Oct. 7, 2017, *available at* https://www.ssnewstelegram.com/news/opioid-addiction-results-in-one-woman-s-daily-struggle/article_bded4eoa-ab80-11e7-a252-d3f304e26628.html.
[252] CDC, *Prescription Painkiller Overdoses at Epidemic Levels*, Nov. 1, 2011, www.cdc.gov.

effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

274. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curing the opioid epidemic in our country."

275. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion" and is working with partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse. A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

276. In furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, Healthcare Distribution Management Association (HDMA)[253] and National Association of Chain Drugstores (NACDS), filed an amicus brief in *Masters Pharmaceuticals*, which claimed that HDMA and NACDS members guard against diversion of controlled prescription drugs as responsible members of society, and that, "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that

[253] Now known as the Healthcare Distribution Alliance (HDA), a trade association of pharmaceutical distributors to which Distributor Defendants belong.

is available to them in the ordering process."[254]

277. Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. Yet, in 2017, even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written promise not to do so.

278. In 2017, Distributor Defendant McKesson publicly acknowledged its essential duty to monitor and to curb to therapeutic levels its distribution of opioid drugs. The chairman and chief executive officer of McKesson, John H. Hammergren, has said: "Pharmaceutical distributors play an important role in identifying and combatting prescription drug diversion and abuse… McKesson, as the nation's largest distributors, takes our role seriously."[255]

279. In an October 31, 2017 letter to Chris Christie, Chair of the President's Commission on Fighting the Drug and Opioid Crisis, Mr. Pete Slone, the Senior Vice President, Public Affairs, of McKesson admitted that the opioid crisis was the "public health crisis of our times" and was affecting communities at alarming rates. [256]Mr. Slone stated that both manufacturers and distributors should address the complicated opioid heath crisis.[257] Certainly in public McKesson admits its responsibility and duty to the public with regard to distributing and disbursing opioids. It is only when McKesson is named in a lawsuit that it is suddenly blameless and has no

[254] Brief for HDMA and NACDS, *Masters Pharms., Inc. v. U.S. Drug Enf't Admin.,* Case No. 15-1335, 2016 WL 1321983 (D.C. Cir. April 4, 2016), at *3-4, *25.
[255] Charles Ornstein, *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, APR, Health News, Jan. 27, 2017; Letter from Pete Slone, Senior Vice President, Public Affairs, of McKesson, to The Honorable Chris Christie dated October 31, 2017.
[256] Pete Slone Letter, *supra*.
[257] *Id.*

responsibilities in stemming the tide of the opioid epidemic it helps fuel.

280. Amerisource agrees it has the same essential duty to monitor and to refrain from supplying suspicious opioid prescribing. On December 14, 2017, a press release announced that Amerisource, as a global healthcare solutions leader, "plays a critical role in the pharmaceutical supply chain, working as a link between manufacturers and healthcare providers to help patients have access to the medications they ***need,*** when they ***need*** them."[258] (Emphasis added).

281. Indeed, Amerisource's website is dedicated to its role as the "core strength" in U.S. drug distribution citing its "[t]remendous cash generation" and its "[d]iverse base of high quality provider customers."[259] Recognizing that the opioid epidemic could strike as many as 650,000 Americans over the next decade, Amerisource's CEO, Steve Collis, has assured the public that distributors like Amerisource are responsible for safely delivering medication to pharmacies given its "unique perspective into how [the] supply chain works."[260]

282. Mr. Collis agrees with people who are "rightfully demanding action on this tragic issue" and agrees to "push forward practical solutions that can yield results in the near-term on opioids."[261] Remarking that it is "difficult to avoid the epidemic of opioid abuse," Mr. Collis adds that the opioid crisis is "demands attention, action, and accountability." [262]Mr. Collis explains that large pharmaceutical distribution companies, of which Amerisource is one, should be held accountable because "nearly every prescription in the United States moves through distributors

[258] AmerisourceBergen Foundation, *AmerisourceBergen Foundation Launches Municipal Support Program to Help Combat Opioid Abuse*, Dec. 14, 2017 press release.
[259] Amerisource Bergen, *Distributor's Duty*, www.amerisourcebergen.com.
[260] Steven H. Collis, *Sound Policy and More Transparency can Help Companies Fight the Opioid Crisis*, Politics, Dec. 15, 2017.
[261] *Id.*
[262] Steve Collis, *The Surprising Morality of Opioid Distribution*, Sept. 18, 2017, *available at* https://www.amerisourcebergen.com/abcnew/fighting-the-opioid-epidemic.

who purchase drugs from pharmaceutical manufacturers and sell them to pharmacies…."[263] Mr. Collis explains that distributors like Amerisource "must create a supply chain that is safe and secure."[264] Mr. Collis even admits that as more opioid-based pain treatments were prescribed, more opioids were distributed.[265] The same views are expressed on Amerisource's website.[266]

283. On its website, Amerisource demonstrates that Distributor Defendants' ability to create a safe and secure supply chain is possible through "complex algorithms to identify and stop orders that are deemed to be suspicious."[267] Mr. Collis admits that Amerisource has "reported and stopped ***tens of thousands*** of suspicious orders since 2007, not to mention countless other orders that pharmacies never had the opportunity to place because [Amerisource] declined to service them altogether."[268] But not in Rockwall County.

284. Cardinal acknowledges on its website that the "opioid abuse crises dates back decades" and is due to "changes in prescribing patterns" for pain.[269] Like McKesson, Cardinal admits that the opioid epidemic is a "serious and complex" public health issue.[270]

285. Cardinal has been aware of this public health crisis for many years because it tracks and reports CDC opioid prescription and overdose death data. For example, Cardinal cites the fact that in 2015, 4.4 billion opioid prescriptions were filled, which equals about 12 prescriptions per person in the United States.[271] Out of these prescriptions, 11% were prescribed following surgery, injury, or for health conditions such as cancer.[272] Moreover, Cardinal recites that 1 in 4 patients

[263] *Id.*
[264] *Id.*
[265] *Id.*
[266] https://www.amerisourcebergen.com/abcnew/fighting-the-opioid-epidemic.
[267] *Id.*
[268] *Id.* (emphasis added).
[269] Cardinal Health, *No Demographic Group is Immune to this Crisis,* www.cardinalheatlh.com.
[270] *Id.*
[271] *Id.*
[272] *Id.*

using opioids long-term in a primary care situation struggle with opioid addiction.[273] Cardinal is also aware that in 2015, according to the CDC, there were more than 33,000 deaths that involved prescribed and non-prescribed opioids, and that opioid overdoses have quadrupled since 1999.[274]

286. To deny such knowledge would be to deny Cardinal's role. Cardinal is part of a "multi-faceted and highly regulated healthcare system" in which "everyone in that chain, including [Cardinal] must do their part."[275] Cardinal believes it has a responsibility to provide a safe and secure channel to deliver medications, such as opioids.[276] This belief is underscored by Cardinal's Opioid Acton Program: Reclaiming Our Communities in which Cardinal states on its website that it operates a "state-of-the-art, constantly adaptive system to combat opioid diversion."[277] Cardinal claims it knows its pharmacy customers and uses a "multi-factor process to evaluate pharmacies" even before the pharmacies become Cardinal's customers.[278] To identify diversion and flag suspicious activity, Cardinal "engage[s] directly with pharmacists to understand their business, their purchasing patterns, the ration of controlled to non-controlled substances ordered and the demographics of their customers."[279] As a result, not only could Cardinal identify the suspicious ordering patterns in Rockwall County, it had the power to stop the influx of opioids into Rockwall County.

287. Cardinal electronically monitors every order prior to fulfillment, especially

[273] *Id.*
[274] *Id.*
[275] Cardinal Health, *Cardinal Health's Commitment to Opioid Anti-Diversion, Education and Misuse Prevention,* www.cardinalhealth.com.
[276] Cardinal Health, *No Demographic Group, supra.*
[277] Cardinal Health, *Opioid Action Program: Reclaiming our Communities,* www.cardinalhealth.com.
[278] *Id.* (making announced and unannounced site visits to pharmacies, which also includes hiring independent investigators specializing in pharmacy diversion and surveillance).
[279] *Id.*; Cardinal also uses an investigative team to perform on-the-ground investigations to determine whether heightened scrutiny is necessary. *Id.* For high-volume orders or orders that flag additional scrutiny, Cardinal has a senior committee of anti-diversion experts who recommend safeguards, which can include ending a business relationship with a customer or denying a business relationship with a new customer. *Id.*

controlled substances.[280] As a distributor, Cardinal has access to, and checks, the requisite information to see "whether the order deviates from historic ordering patterns in [Cardinal's] strict anti-diversion standards."[281] Suspicious orders are flagged for further "scrutiny and evaluation, including potentially canceling the order."[282]

288. Cardinal states on its website that it "refuse[s] to supply controlled substances to any pharmacy customer where [Cardinal] believe[s] there is an unreasonable risk of medication diversion."[283] This refusal is part of Cardinal's commitment to help solve the "complex national public health crisis."[284] Yet Cardinal continued to supply opioids to pharmacies in Rockwall County despite the data it reviewed.

289. Distributor Defendants knew their duty. Distributor Defendants had the means to carry out their duty and claim to have successfully done so at times in the past. Distributor Defendants acknowledge that their duty is ongoing. With regards to opioids, however, Distributor Defendants continuously evade their gatekeeping duties, including but not limited to, in Rockwall County.

290. According to *The Charleston Gazette-Mail*, Distributor Defendants shipped nearly 9 million hydrocodone pills over two years to one pharmacy in the town of Kermit, West Virginia.[285] Kermit, West Virginia has a population of 392. Drug wholesalers distributed 780 million pills of oxycodone and hydrocodone in the state over six years. According to the *Gazette*, "[t]he unfettered shipments amount to 433 pain pills for every man, woman and child in West

[280] *Id.*
[281] *Id.*
[282] *Id.*
[283] Cardinal Health, *Cardinal Health's Commitment, supra.*
[284] *Id.*
[285] Charles Ornstein, *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, APR, Health News, Jan. 27, 2017.

Virginia."[286]

291. Refusing to take action or turning a blind eye to suspicious spikes in opioid prescriptions has for the Distributor Defendants simply become a pesky cost of doing business. McKesson and Cardinal did not take sufficient heed of the multi-million dollar fines each had paid in 2008. McKesson agreed to pay a $150 million fine on January 17, 2017. Cardinal Health reached a $44 million settlement in December 2016; Cardinal also agreed in January 2017 to pay $20 million to the state of West Virginia; and Amerisource agreed to pay $16 million to the state of West Virginia.[287]

292. According to a 60 Minutes/Washington Post joint investigation, "[t]he pharmaceutical industry is doing everything it can to keep [the opioid] epidemic going."[288] McKesson certainly did not recognize any sort of "due diligence" while it was providing "millions and millions and millions of pills to countless pharmacies through the United States."[289] Since the 1990s, McKesson has made billions from distributing addictive opioids.[290] McKesson has admitted that when it came to the opioid crisis and pills flooding American communities, there was plenty of blame to go around, including drug makers, other distributors, doctors, and pharmacies.[291]

293. If McKesson had used their authority in the supply chain, the opioid epidemic would not be "nowhere near" where it is today.[292] In McKesson's role as a distributor, not a day went by that something suspicious was not happening, but McKesson never reported any

[286] *Id.*
[287] Ornstein, *supra.*
[288] 60 Minutes, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor,* CBS News, Dec. 17, 2017.
[289] *Id.*
[290] *Id.*
[291] *Id.*
[292] *Id.*

suspicious activity, according to the 60 Minutes investigation.[293] McKesson "fueled the explosive prescription drug abuse problem in this country."[294]

294. McKesson repeatedly filled suspicious orders of the most commonly abused and prescribed opioid drugs oxycodone and hydrocodone.[295] McKesson, as did other Distributor Defendants, failed in their duty to act and also violated the Texas Controlled Substances Act.

295. Distributor Defendants have knowingly distributed, delivered, or dispensed a controlled substance in violation of the Texas Controlled Substances Act §481.128(a)(1). Distributor Defendants dispensed or delivered a controlled substance without any valid medical purpose. Tex. Health & Safety Code §481.071. Upon information and belief, Distributor Defendants knew of or had notice of a suspicious rise in the prescribing of opioids in Rockwall County, but chose to open opioid floodgates rather than regulate them. Pill-mill doctors need Distributors to be complicit in the over-supply of opioids. Distributor Defendants were so, causing damages to Rockwall County.

296. Distributor Defendants were in a unique position to see the results of Manufacturing Defendants' fraudulent marketing scheme. Distributor Defendants knew or should have known that there was a sharp increase in the prescription and distribution of opioids. Distributor Defendants undertook the responsibility to prevent opioids from being dispensed or disbursed for diversionary purposes − with a multi-faceted system to monitor and prevent they developed long ago, *according to their own published public proclamations* – and breached that duty. Like Manufacturing Defendants, Distributor Defendants chose profits over duty, in breach of duty.

I. Defendants Coordinated their Efforts to Deceive the Public.

[293] 60 Minutes, *supra.*
[294] Too Big to Prosecute, *supra*.
[295] *Id.*

303. Manufacturing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide, and the HDA includes a "Contracts and Chargebacks Working Group," suggesting a standard practice.

304. Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

305. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding.

306. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.

307. The HDA led to the formation of interpersonal relationships and an organization among the Defendants. The HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturing Defendants by advocating for the many benefits of members, including "strengthen[ing] . . . alliances."[296]

308. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[297]

[296] *Manufacturer Membership,* Healthcare Distribution Alliance, https://www.hda.org/about/membership/manufacturer.
[297] *Id.*

309. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year end net sales" through wholesale distributors, including AmerisourceBergen, Cardinal Health, and McKesson.

310. The HDA also offers a multitude of conferences. The Manufacturing Defendants embraced this opportunity by attending and sponsoring these events.[298]

311. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including the Industry Relations Council, Business Technology Committee, Logistics Operation Committee, Manufacturer Government Affairs Advisory Committee, and Contracts and Chargebacks Working Group.

312. The Distributor and Manufacturing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers . . . ." The Manufacturing Defendants used this information to gather high-level data regarding overall distribution and direct Distributor Defendants on how to most effectively sell prescription opioids.

313. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members

[298] *2015 Distribution Management Conference and Expo,* Healthcare Distribution Alliance.

contribut[ing] to the development of this publication" beginning in late 2007.

VII. CAUSES OF ACTION

NEGLIGENT AND/OR INTENTIONAL CREATION OF A PUBLIC NUISANCE AGAINST MANUFACTURING AND DISTRIBUTOR DEFENDANTS

314. Rockwall County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

315. Manufacturing Defendants knowingly encouraged doctors in and around Rockwall County to prescribe, and residents to use, highly addictive opioids for chronic pain even though Manufacturing Defendants knew using opioids had a high risk of addiction and reduced quality of life. Distributor Defendants knew or should have known that many of those prescription orders were not for a valid medical purpose. Nevertheless, Distributor Defendants continued to disburse and distribute opioids even though upon information and belief, the evidence would suggest suspicion for diversionary purposes.

316. By doing so, Defendants purposefully interfered with Rockwall County's public health, public safety, public peace, public comfort, and public convenience.

317. Defendants, individually and in concert with each other, have contributed to and/or assisted in creating and maintaining a condition that is harmful to the health and safety of Rockwall County residents, and/or unreasonably interferes with the peace and comfortable enjoyment of life in violation of Texas law.

318. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community – and the harm inflicted outweighs any offsetting benefit.

319. The staggering rates of opioid use resulting from Manufacturing Defendants' marketing efforts, combined with the high number of opioids distributed by Distributor

Defendants, have caused, and continues to cause, harm to the community including, but not limited to:

a) Upwards of 30% of all adults use opioids. These high rates of use have led to unnecessary opioid addiction, overdose, injuries, and deaths;

b) Children have been exposed to opioids prescribed to family members or others resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among Rockwall County teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure causing severe withdrawal symptoms and lasting developmental impacts;

c) Residents of Rockwall County, who have never taken opioids, have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids and the loss of companionship, wages, or other support from family members who have used, become addicted to, overdosed on, or been killed by opioids;

d) More broadly, opioid use and addiction have driven Rockwall County residents' health care costs higher;

e) Employers have lost the value of productive and healthy employees who have suffered from adverse consequences from opioid use;

f) Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them;

g) This demand has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process;

h) Diverting opioids into secondary, criminal markets and increasing the number of individuals who are addicted to opioids has increased the demands on emergency services and law enforcement in Rockwall County;

i) All of Defendants' actions have caused significant harm to the community – in lives lost; addictions endured; the creation of an illicit drug

market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes;

j) These harms have taxed the human, medical, public health, law enforcement, and financial resources of Rockwall County; and

k) Defendants' interference with the comfortable enjoyment of life of a substantial number of people is entirely unreasonable because there is limited social utility to opioid use and any potential value is outweighed by the gravity of harm inflicted by Defendants' actions.

320. Manufacturing Defendants knew, or should have known, that promoting opioid use would create a public nuisance in the following ways:

a) Defendants have engaged in massive production, promotion, and distribution of opioids for use by the citizens of Rockwall County;

b) Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management;

c) Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs; and

d) Defendants knew, or should have known, that their promotion would lead to addiction and other adverse consequences that the larger community would suffer as a result.

321. Manufacturing Defendants' actions were, at the least, a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain thereby causing opioids to become widely available and used in Rockwall County.

322. Without Defendants' actions, opioid use would not have become so widespread and the enormous public health hazard of opioid addiction would not have existed and could have been averted.

323. The health and safety of the citizens of Rockwall County, including those who use, have used, or will use opioids, as well as those affected by opioid users, is a matter of great public interest and legitimate concern to Rockwall County's citizens and residents. It was foreseeable to

all Defendants that the burden of the opioid crisis would fall to counties like Rockwall County in the form of social and economic costs. Specifically, it was foreseeable that Rockwall County would sustain damages as an employer obligated to provide healthcare coverage to its employees and as a local government obligated to provide public services to its citizens.

324. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

325. Defendants' conduct has affected and continues to affect a considerable number of people within Rockwall County and is likely to continue to cause significant harm to patients who take opioids, their families, and the community at large.

326. Each Defendant created or assisted in creating the opioid epidemic, and each Defendant is jointly and severally liable for its abatement. Furthermore, each Defendant should be enjoined from continuing to create, perpetuate, or maintain said public nuisance in Rockwall County. Furthermore, Defendants should compensate Rockwall County for the funds it has expended and continues to expend for medical insurance claims for opioids that were not medically valid, as well as increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities.

COMMON LAW FRAUD AGAINST ALL DEFENDANTS

327. Rockwall County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

328. At all relevant and material times, Defendants expressly and/or impliedly warranted that opioids were safe, of merchantable quality, and fit for use.

329. Manufacturing Defendants' superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and

dangers of opioids, and its intentional dissemination of promotional and marketing information about opioids for the purpose of maximizing sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with opioids.

330. At all relevant and material times, Manufacturing Defendants, individually and acting through their employees and agents, and in concert with each other, fraudulently represented to physicians, who Defendants knew would justifiably rely on Manufacturing Defendants' representations, that opioids were safe and effective for treating chronic pain.

331. Manufacturing Defendants' false representations were fraudulently made, with the intent or purpose that healthcare providers and patients would justifiably rely upon them, leading to the prescription, administration, filling, purchasing, and consumption of opioids in Rockwall County.

332. Distributor Defendants knowingly and deliberately took advantage of the Manufacturing Defendants' false and fraudulent representations to disburse and distribute an immense amount of opioids in Rockwall County.

333. Distributor Defendants made representation that they were taking action to prevent the opioid oversupply and abuse while recognizing they were in a unique position to do so. Rockwall County relied on Distributor Defendants to act as a gatekeeper in the supply chain as they represented to the public.

334. Defendants' deliberate misrepresentations and/or concealment, suppression, and omission of material facts as alleged herein include, but are not limited to:

a) Making false and misleading claims regarding the known risks of the addictive nature of opioids and suppressing, failing to disclose, and mischaracterizing the addictive nature of opioids and in concomitant costs, such as overdoses, deaths, and heroin addiction;

b) Making false and misleading written and oral statements that opioids are more effective than traditional pain killers for chronic pain, or effective at all and/or omitting material information showing that opioids are no more effective than other non-addictive drugs for chronic pain;

c) Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of using opioids;

d) Making false and misleading claims downplaying the risk of addiction when using opioids and/or setting forth guidelines that would purportedly identify addictive behavior;

e) Making false and misleading misrepresentations concerning the safety, efficacy and benefits of opioids without full and adequate disclosure of the underlying facts which rendered such statements false and misleading; and

f) Disbursing and distributing opioids when suspicion existed that opioids were being diverted.

335. Defendants willfully, wantonly, and recklessly disregarded their duty to provide truthful representations regarding the safety and risk of opioids and distributed and disbursed opioids, including the fact that upon information and belief, there was suspicion for diversionary purposes.

336. Defendants made these misrepresentations with the intent that the healthcare community and patients would rely to their detriment.

337. Defendants' misrepresentations were made with the intent of defrauding and deceiving the medical community and consumers to induce and encourage the sale of opioids.

338. Defendants' fraudulent representations evidence their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers living in Rockwall County.

339. Defendants omitted, misrepresented, suppressed and concealed material facts concerning the dangers and risk of injuries associated with the use of opioids, as well as the fact that the product was unreasonably dangerous.

340. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

341. Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of opioids.

342. Defendants' failure to stem, rather than fuel spikes of opioid sales was intended to encourage the sale of opioids, even if the circumstances provided suspicion for diversionary purposes.

343. The treating medical community and consumers in Rockwall County did not know that Defendants' representations were false and/or misleading and justifiably relied on them.

344. Defendants had sole access to material facts concerning the dangers and unreasonable risks of opioids, which they intentionally concealed.

345. As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment of facts, upon which the medical community and consumers in Rockwall County reasonably relied, Rockwall County suffered actual and punitive damages.

NEGLIGENCE AGAINST MANUFACTURING AND DISTRIBUTING DEFENDANTS

346. Rockwall County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

347. Manufacturing Defendants have a duty to exercise reasonable care in marketing its opioids to physicians treating residents of Rockwall County and Rockwall County residents.

Manufacturing Defendants have breached their duty by knowingly and fraudulently misrepresenting the benefits of, and downplaying the risks of, opioids for chronic pain.

348. Manufacturing Defendants have used deceitful marketing ploys, KOLs, Front Groups, and other schemes to increase profits at the cost of public health causing an opioid epidemic. Manufacturing Defendants have acted willfully, wantonly, and maliciously.

349. Likewise, Distributor Defendants have a duty to exercise ordinary care in distributing opioids. Distributor Defendants have breached their duty by failing to prevent or reduce the distribution of opioids even if there existed suspicion for diversionary purposes. Distributor Defendants have intentionally failed to prevent or reduce the distribution of opioids so that they could increase profits. Distributor Defendants have acted willfully, wantonly, and maliciously.

350. As a proximate result, Manufacturing and Distributor Defendants and its agents have caused Rockwall County to incur excessive costs to treat the opioid epidemic in its county including, but not limited to, increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities. It was foreseeable to all Defendants that the burden of the opioid crisis would fall to counties like Rockwall County in the form of social and economic costs. Specifically, it was foreseeable that Rockwall County would sustain damages as an employer obligated to provide healthcare coverage to its employees and as a local government obligated to provide public services to its citizens.

351. Rockwall County and its residents are therefore entitled to actual and punitive damages.

GROSS NEGLIGENCE AGAINST MANUFACTURING AND DISTRIBUTING DEFENDANTS

352. Rockwall County re-alleges and incorporates by reference each of the allegations

contained in the preceding paragraphs of this Complaint as though fully alleged herein.

353. Defendants' marketing scheme to optimize profits by misrepresenting and falsely promoting opioids as the panacea to chronic pain was done intentionally.

354. Defendants' hiring of KOLs, Front Groups, and others to spread its fraudulent message that opioids were useful and beneficial for chronic pain was grossly negligent and done with conscious indifference or reckless disregard for the safety of others.

355. Distributor Defendants' distribution of opioids despite the obvious signs that there was no valid medical purpose for a large number of prescriptions for opioids was grossly negligent and done with conscious indifference or reckless disregard for the safety of others.

356. Each Defendant's actions and omissions as described herein, singularly or in combination with each other, were malicious resulting in damages and injuries to Rockwall County and its residents.

357. At every stage, Defendants knew, or should have known, that their conduct would create an unreasonable risk of physical harm to others, including Rockwall County and its residents, and should be held liable in punitive and exemplary damages to Rockwall County.

TEXAS CONTROLLED SUBSTANCES ACT ("TCSA") AGAINST DISTRIBUTOR DEFENDANTS AND INDIVIDUAL DEFENDANTS

358. Rockwall County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

359. Distributor Defendants have knowingly distributed, delivered, administered, or dispensed a controlled substance in violation of the Texas Controlled Substances Act §481.128(a)(1) by dispensing or delivering a controlled substance, or causing a controlled substance to be administered, when there is no valid medical purpose. Tex. Health & Safety Code §481.071.

360. As alleged herein, each Distributor Defendant, at all times relevant to this Complaint, had a duty to monitor the flow of opioids by acting as a gatekeeper between physicians and pharmacies and patients. Distributor Defendants wholly failed in its duty and knew, or should have known, that they were distributing or disbursing opioids without a valid medial purpose.

361. Moreover, Distributor Defendants' failure to rein in the endless supply of opioids was reasonably calculated to deceive practitioners treating Rockwall County residents into prescribing opioids without any valid medical purpose, and Distributor Defendants continue to do so to this day.

362. Individual Defendants prescribed opioids without a valid medical purpose in violation of Texas Health & Safety Code Section 481.071(a).

363. As a direct and proximate cause of Distributor Defendants' and Individual Defendants' deceptive conduct, Rockwall County should be awarded civil penalties pursuant to the Texas Controlled Substances Act.

TEXAS CONTROLLED SUBSTANCES ACT ("TCSA") AGAINST DISTRIBUTOR DEFENDANTS

365. Rockwall County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

366. Distributor Defendants have knowingly distributed opioids even though it had reason to suspect that the opioids were being diverted, or suspicion for diversionary purposes.

367. As alleged herein, each Distributor Defendant, at all times relevant to this Complaint, has stated in public through its agents and on its websites that they act as gatekeepers between physicians and pharmacies and patients. In fact, Distributor Defendants have called their role in the chain of supply critical to stopping suspicious opioid prescribing and assisting in stopping the opioid epidemic.

368. For many years, Distributor Defendants have had the ability to track prescription orders and they have undertaken the duty to exercise reasonable care to track and halt any and all suspicious opioid prescriptions. Distributor Defendants claim they have stopped tens of thousands of prescriptions suspected of diversion while admitting that the opioid epidemic is a serious public health crisis.

369. But Distributor Defendants have breached its duty by failing to track and halt the overwhelming supply of opioids into Rockwall County despite its layers of oversight and commitment to provide a safe and secure channel to deliver medications, including opioids. Distributor Defendants have intentionally failed to prevent or reduce the distribution of opioids so that they could increase profits and have done so willfully, wantonly, and maliciously.

370. As a proximate result, Distributor Defendants and its agents have caused Rockwall County to incur excessive costs to treat the opioid epidemic in its county including, but not limited to, increased costs of social services, health systems, law enforcement, judicial system, and treatment facilities. It was foreseeable to all Defendants that the burden of the opioid crisis would fall to counties like Rockwall County in the form of social and economic costs. Specifically, it was foreseeable that Rockwall County would sustain damages as an employer obligated to provide healthcare coverage to its employees and as a local government obligated to provide public services to its citizens.

371. Rockwall County and its residents are therefore entitled to actual and punitive damages.

UNJUST ENRICHMENT AGAINST ALL DEFENDANTS

372. Rockwall County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

373. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by Rockwall County and its residents.

374. When Rockwall County and its residents purchased opioids, they expected that Defendants had provided necessary and accurate information regarding those risks. Instead, Defendants had misrepresented the material facts regarding the risks and benefits of opioids and distributed or disbursed opioids even though, upon information and belief, there was suspicion for diversionary purposes.

375. Defendants took undue advantage and received a benefit because the County bore the cost of the externalities of Defendants' wrongful conduct. Moreover, the County had no choice and was effectively required to cover these costs to Defendants' benefit.

376. Defendants have been unjustly enriched at the expense of Rockwall County, and Rockwall County is therefore entitled to damages to be determined by the jury.

CIVIL CONSPIRACY AGAINST ALL DEFENDANTS

377. Rockwall County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

378. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution of opioids into Texas and Plaintiff's community.

379. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing of opioids and/or distribution of opioids into Texas and Plaintiff's community.

380. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

381. The Manufacturing Defendants further unlawfully marketed opioids in Texas and Plaintiff's community in furtherance of that conspiracy.

382. Defendants, in coordinated and concerted action with each other, engaged in a joint scheme to materially expand opioid use by altering the medical community's prescribing practices of opioids through repeated fraudulent statements and misrepresentations. The Defendants used front groups, Key Opinion Leaders, and sale representatives to spread their false message under the guise of being authoritative and neutral third parties. Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system, but rather, operated together as one united entity, working together on multiple fronts to engage in the unlawful sale of prescription opioids.

383. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

384. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

385. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

386. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

387. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the Conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct has a great probability of causing substantial harm. Manufacturing Defendants' fraudulent wrongdoing was also particularly gross.

388. Defendants' misconduct alleged in this case is ongoing and persistent.

389. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

390. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

391. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre-and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays:

a. That the acts alleged herein be adjudged and decreed to be unlawful and that the Court enter a judgment declaring them to be so;

b. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Texas law;

c. That Plaintiff recover all measures of damages, including punitive and exemplary damages, allowable under the law, and that judgment be entered against Defendants in favor of Plaintiff;

d. That Plaintiff recover restitution on behalf of Rockwall County consumers who paid for opioids for chronic pain;

e. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law; and

f. That Defendants be ordered to abate the public nuisance that they created in in violation of Texas common law.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Date: April 10, 2019

Respectfully Submitted,

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